EXHIBIT 114

The Per Diem Costs of Home Infusion Therapy Services

Final Report

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Prepared for
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The National Home Infusion Association (NHIA) contracted with Abt Associates, Inc. to conduct a survey and analysis of the per diem costs associated with providing home infusion therapy services. This report, written by Abt Associates, Inc., is made available for purchase by NHIA. Contact NHIA at (703)549-3740 or www.nhianet.org.

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Executive Summary

The National Home Infusion Association (NHIA) contracted with Abt Associates, Inc. to conduct a survey and analysis of the per diem costs associated with providing home infusion therapy services.

The Home Infusion Therapy Pharmacy Clinical Services Model

Providers of home infusion therapy are licensed pharmacies. They provide a wide range of services required to safely and effectively administer home infusion and nutritional therapies, specialty drugs, and disease state and care management services. Accreditation is often a payer requirement in contracting for the provision of home infusion therapy services, and the vast majority of these pharmacies are typically accredited by the Accreditation Commission for Health Care, the Community Health Accreditation Program, or the Joint Commission on Accreditation of Healthcare Organizations. These organizations set standards for quality care and survey the providers for compliance with the standards (see Appendix A). Accreditation reflects the reality that the clinical service model provided by specialized home infusion pharmacies is notably different than that of traditional community retail pharmacies.

The concise but comprehensive description of a home infusion therapy pharmacy that is contained in a national code set[1] used in HIPAA health care claim transactions also reflects the clinical service model:

> ***Home Infusion Therapy Pharmacy***. *Pharmacy-based, decentralized patient care organization with expertise in USP 797-compliant sterile drug compounding that provides care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics and nutritional formulae administered through catheters and/or needles in home and alternate sites. Extensive professional pharmacy services, care coordination, infusion nursing services, supplies and equipment are provided to optimize efficacy and compliance.*

The Home Infusion Therapy Per Diem: One of Three Components of Cost

As observed in the results of the survey reported later, the costs associated with providing the services, supplies, and equipment differ based on the complexity of the infusion therapy and the supplies and equipment generally required for safe and effective administration of the therapy. These significant variations in cost by therapy are reflected in the prevailing reimbursement methodology used by private sector and certain government health plans[2]. Correspondingly, the reimbursement methodology differs considerably from the dispensing fee payment methodology associated with traditional community retail pharmacy drug dispensing.

[1] The "taxonomy" code set is maintained by the National Uniform Claims Committee (www.nucc.org).

[2] Government managed care plans (Medicare Advantage plans and Medicaid managed care organizations) generally use the private sector's reimbursement methodology for provision of home infusion therapy.

For home infusion therapy, the prevailing methodology divides home infusion reimbursement into three components:

- All drugs provided during home infusion therapy;
- Direct infusion nursing services provided to home infusion patients in their homes; and
- Per diem – all other services (e.g., referral processing, intake qualification and documentation setup, care coordination, verifying physician order set, sterile compounding, packaging, delivery, patient education, clinical monitoring, insurance administration, etc.), supplies and equipment provided in conjunction with home infusion therapy.[3]

In the NHIA National Definition of Per Diem, the term "per diem" represents each day that a given patient is provided access to a prescribed therapy, beginning with the day the therapy is initiated and ending with the day the therapy is permanently discontinued. The per diem is not a one-time payment triggered by the dispensing of the drug. The clinical services covered by the per diem are not single steps that are completed with the first dose. Rather, they are ongoing activities that continue until the patient is discharged from care.

Nationally used, HIPAA-compliant HCPCS "S" per diem billing codes are published by the Centers for Medicare & Medicaid Services for a wide range of home infusion therapies[4]. These per diem codes specifically include administrative services, professional pharmacy services, care coordination, and necessary supplies and equipment. (The other two cost components of home nursing visits and drugs are billed separately.) The compilation in this report of detailed survey data is done by grouping the cost data into the available HCPCS S codes.

The NHIA National Definition of Per Diem[5], which was provided to survey respondents, lists the many services, supplies and equipment included in the per diem along with certain products and services billed separately. The National Definition of Per Diem in effect in 2005 and used in the survey instrument is provided in Appendix B.

[3] Under per diem billing, there are a limited number of occasions where supplies are also separately billed. These exceptions are discussed under the NHIA National Definition of Per Diem included in Appendix B.

[4] The NHIA National Coding Standard for Home Infusion Claims under HIPAA is a widely used document that provides procedures for use of these codes and is obtained from www.nhianet.org.

[5] NHIA periodically updates the NHIA National Definition of Per Diem. The current version is posted at www.nhianet.org/perdiemfinal.htm.

Survey Methodology

This study collected information to allow the estimation of per diem costs by therapy. Costs are defined as the value of the labor, supplies, overhead and other resources as detailed in the NHIA National Definition of Per Diem needed to provide home infusion per diem services, not the payment rates at which these services are reimbursed.

A survey instrument was developed and sent out in mid-April of 2005 to five national and 28 randomly selected other home infusion therapy providers. Ultimately, we received seven usable responses, including responses from all five national providers and two of the other randomly selected providers. Almost all of the responding providers (respondents) reported providing home infusion therapy services in more than one state and in aggregate they consisted of at least 179 home infusion therapy pharmacies. As a result, collectively the survey respondents provided home infusion therapy services in all 50 states and the District of Columbia. While most respondents provided information on their entire home infusion therapy operations, one respondent reported information separately for eight (8) of its subsidiary operations. Thus, the seven respondents provided 14 (six plus eight) surveys, providing information for the calendar year 2004 (January 1, 2004 to December 31, 2004). In summary:

- Survey results reflected data covering the operations of at least 179 home infusion therapy pharmacies providing services in all 50 states.

Per diem cost estimates for each S code were calculated as follows:

- The direct, "bottom up" costs – labor, supply, pump and pump kit, and delivery costs were estimated for each S code for each respondent;
- The respondent's reported total per diem costs were used in a "top down" adjustment both to validate the bottom up calculations as well as to assure that costs not accounted for in the bottom up cost estimates (e.g., overhead, rent, etc.) are captured; and
- Mean per diem costs across providers were calculated, weighted for their probability of being selected and responding to the survey and for their total per diem costs (sample and cost weighting).

A review panel of home infusion therapy providers and other experts reviewed and vetted the study's methodology and aggregated results.

Results and Conclusions

There were three strong findings for the resulting per diem cost estimates:

- Mean per diem costs varied greatly across codes, even within therapy code families, strongly indicating the importance of using a comprehensive series of S codes to define different home infusion services. To illustrate, survey results for anti-infectives illustrate the variance within the therapy code family of anti-infectives:

S Code		Mean Per Diem Cost	Mean Per Diem Cost Adjusted to 2005 Using CPI-U	C.V.
Anti-Infectives: Antibiotics, Antifungals, Antivirals				
S9497	Q3 Hours	$102	$107	0.34
S9504	Q4 Hours	$100	$104	0.33
S9503	Q6 Hours	$94	$98	0.32
S9502	Q8 Hours	$77	$81	0.27
S9501	Q12 Hours	$77	$80	0.26
S9500	Q24 Hours	$70	$73	0.27
S9494	Unspecified	$76	$79	0.27

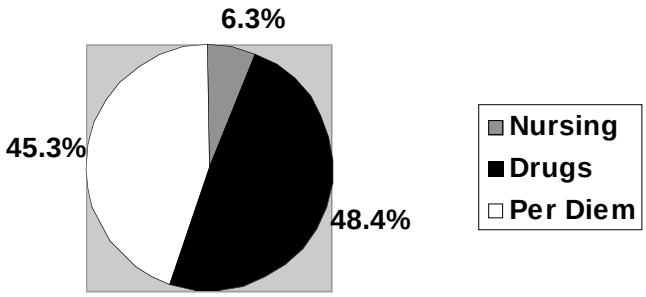
- There was very little variation in the cost estimates for each code across providers – the unweighted coefficients of variation (c.v.) across the 14 respondents varied from 0.20 to 0.52 – cost variation usually is not considered to be a significant problem unless c.v.'s exceed 1.00.[6]
- It is noted earlier that services necessary for home infusion therapy are notably different than those provided from traditional community retail pharmacies. As compared to much lower dispensing fees typically reimbursed to traditional community retail pharmacies for filling prescriptions, the average direct cost for the delivery component alone was found to be $38.25.[7] In addition to delivery, the many other incurred costs--referral processing, intake qualification and documentation setup, care coordination, verifying physician order set, sterile compounding, packaging, patient education, clinical monitoring, insurance administration, etc.—are reported in the per diem costs.

[6] The coefficient of variation is the ratio of the standard deviation to the mean per diem cost.

[7] This "direct" average delivery cost does not include any top-down adjustment for overhead and indirect costs. Home infusion therapy drugs and equipment often must be delivered to multiple, distant locations, as a opposed to a central "neighborhood" for a community pharmacy.

Respondents also were asked to report their total costs for nursing, drugs, and per diem services. Shares of total costs for those who responded were as follows in 2004:

Percentage of Home Infusion Therapy Costs: Nursing, Drugs, and Per Diem For Responding Providers



These cost shares demonstrate that home infusion therapy pharmacies provide products and services well beyond just the drugs, including home infusion nursing and everything captured within per diem reporting. Other survey results included the following:

- Nursing cost per visit -- $128[8]
- Delivery cost per service -- $38[9]

This study was the first attempt to estimate home infusion per diem costs by therapy (S code) and may help educate both providers and payers on the resource costs required for provision of home infusion therapies. As previously mentioned, however, home infusion therapy pharmacies also provide drugs and often nursing services to their clients. Future, more comprehensive cost studies should analyze drug and nursing cost measures to complement this study of per diem costs, to offer a more complete picture of the total costs to safely and effectively provide quality home infusion therapy services.

[8] Nursing costs per visit were calculated by dividing reported home infusion nursing costs by nursing visits and may not include overhead and indirect costs.

[9] This "direct" average delivery cost does not include any top-down adjustment for overhead and indirect costs.

1. Introduction

The National Home Infusion Association (NHIA) contracted with Abt Associates, Inc. to conduct a survey and analysis of the per diem costs associated with providing home infusion therapy services. The services necessary for safe and effective administration of home infusion are provided by specialized home infusion pharmacies that are notably different than traditional community retail pharmacies.

1.1 Background on Home Infusion Therapy

Home infusion therapy includes parenteral administration of prescription drugs and biologics via administration routes that are intravenous, intra-spinal, intrathecal, intra-arterial, subcutaneous, or intramuscular. Administration is through catheters and/or needles and is provided in a patient's home or alternate sites. Medications typically provided include compounded solutions for parenteral administration of antibiotics, chemotherapy, pain medications, hydration, enteral and parenteral nutrition, inhalation therapies using nebulizers, and as well as many specialty drug regimens that require a high level of extensive pharmacy professional services to optimize efficacy and compliance. Examples of provided specialty drugs include erythropoietin, growth hormone, infliximab, intravenous immune globulins, palivizumab, low molecular heparin and many more. Infusion therapy always originates with orders from qualified physicians who are overseeing the care of the patient, that are designed to achieve physician-defined therapeutic endpoints.

Medical conditions treated with home infusion therapy include infections of all kinds (such as respiratory, urinary tract, soft-tissue, post-operative infections, and pneumonia); cancer and cancer-related pain; nutrition-related problems (such as from Crohn's disease, esophageal cancer, cerebral palsy, Alzheimer's Disease, and more); AIDS-related conditions (such as anemia, malnutrition, and severe pain); congestive heart failure; immune deficiencies; multiple sclerosis; hemophilia; thalassemia; growth disorders and much more.

Prior to the availability of home infusion therapy in the 1980s, expensive inpatient treatment was the only option for patients needing IV therapies. Driven by heightened emphasis on cost-effectiveness and cost-containment, technological advances enabling safe and effective administration of infusion therapies in the home, and the desire of patients to resume normal lifestyles and work activities while recovering from illness, provision of home infusion services has greatly expanded in size and scope since then.

1.2 The Home Infusion Therapy Pharmacy

Providers of home infusion therapy are licensed pharmacies. They provide a wide range of services required to safely and effectively administer home infusion and nutritional therapies, specialty drugs, and disease state and care management services. Accreditation is often a payer requirement in contracting for the provision of home infusion therapy services, and the vast majority of these pharmacies are typically accredited by the Accreditation Commission for Health Care (www.achc.org), the Community Health Accreditation Program (www.chapinc.org), or the Joint Commission on Accreditation of Healthcare Organizations (www.jcaho.org). These organizations set

standards for quality care and survey the providers for compliance with the standards (see Appendix A).

Like inpatient treatment, home infusion therapy encompasses a wide range of products and services and can be described as a "hospital without walls." As noted by U.S. Congress Office of Technology Assessment in its May 1992 report, Home Drug Infusion Therapy Under Medicare, "An infusion pharmacy differs dramatically from most retail pharmacies. While retail pharmacies generally dispense only oral medication, infusion pharmacies must have the equipment necessary to safely prepare and store parenteral solutions. These include laminar flow hoods to reduce risk of contamination, modified storage areas for certain drugs, and additional supplies and equipment needed for mixing solutions." Home infusion pharmacists are highly skilled in the requirements for providing infusion/specialty drug administration in the home and other alternate sites.

The concise but comprehensive description of a home infusion therapy pharmacy that is contained in a national code set[10] used in HIPAA health care claim transactions also reflects the clinical service model:

> ***Home Infusion Therapy Pharmacy***. *Pharmacy-based, decentralized patient care organization with expertise in USP 797-compliant sterile drug compounding that provides care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics and nutritional formulae administered through catheters and/or needles in home and alternate sites. Extensive professional pharmacy services, care coordination, infusion nursing services, supplies and equipment are provided to optimize efficacy and compliance.*

In addition to professional pharmacy services, home nursing services are provided ensure proper patient education and training and to monitor the care of the patient in the home. These nursing services may be provided directly by infusion pharmacy nursing staff or by a qualified home health agency with expertise in infusion nursing.

1.3 The Home Infusion Therapy Per Diem: One of Three Components of Cost

As observed in the results of the survey reported later, the costs associated with providing the services, supplies, and equipment differ based on the complexity of the infusion therapy and the supplies and equipment generally required for safe and effective administration of the therapy. These significant variations in cost by therapy are reflected in the prevailing reimbursement methodology used by private sector and certain government health plans[11]. Correspondingly, the reimbursement methodology differs considerably from the dispensing fee payment methodology associated with traditional community retail pharmacy drug dispensing.

[10] The "taxonomy" code set is maintained by the National Uniform Claims Committee (www.nucc.org).

[11] Government managed care plans (Medicare Advantage plans and Medicaid managed care organizations) generally use the private sector's reimbursement methodology for provision of home infusion therapy.

For home infusion therapy, the prevailing methodology divides home infusion reimbursement into three components:

- All drugs provided during home infusion therapy;
- Direct infusion nursing services provided to home infusion patients in their homes; and
- Per diem – all other services (e.g., referral processing, intake qualification and documentation setup, care coordination, verifying physician order set, sterile compounding, packaging, delivery, patient education, clinical monitoring, insurance administration, etc.), supplies and equipment provided in conjunction with home infusion therapy.[12]

In the NHIA National Definition of Per Diem[13], the term "per diem" represents each day that a given patient is provided access to a prescribed therapy, beginning with the day the therapy is initiated and ending with the day the therapy is permanently discontinued. The per diem is not a one-time payment triggered by the dispensing of the drug. The clinical services covered by the per diem are not single steps that are completed with the first dose. Rather, they are ongoing activities that continue until the patient is discharged from care.

Nationally used, HIPAA-compliant HCPCS "S" per diem billing codes are published by the Centers for Medicare & Medicaid Services for a wide range of home infusion therapies[14]. These per diem codes specifically include administrative services, professional pharmacy services, care coordination, and necessary supplies and equipment. (The other two cost components of home nursing visits and drugs are billed separately.) The compilation in this report of detailed survey data is done by grouping the cost data into the available HCPCS S codes.

1.4 Report Overview

The NHIA National Definition of Per Diem, which was provided to survey respondents, lists the any services, supplies and equipment included in the per diem along with certain products and services billed separately. The National Definition of Per Diem in effect in 2005 and used in the survey instrument is provided in Appendix B.

This study collected information to allow the estimation of per diem costs for each type of therapy. Costs are defined as the value of the labor, supplies, overhead and other resources as detailed in the NHIA National Definition of Per Diem needed to provide home infusion per diem services, not the payment rates at which these services are reimbursed.

[12] Under per diem billing, there are a limited number of occasions where supplies are also separately billed. These exceptions are discussed under the NHIA National Definition of Per Diem included in Appendix B.

[13] NHIA periodically updates the NHIA National Definition of Per Diem. The current version is posted at www.nhianet.org/perdiemfinal.htm.

[14] The NHIA National Coding Standard for Home Infusion Claims under HIPAA is a widely used document that provides procedures for use of these codes and is obtained from www.nhianet.org.

This study collected information to allow the estimation of per diem costs for each type of therapy and other services. Subsequent analyses of the survey data were then used to calculate per diem cost estimates service by service. The remainder of the report is organized as follows:

- Section 2 discusses the survey and data collection;
- Section 3 describes the methodology used to calculate the per diem cost estimates;
- Section 4 presents the study's findings; and
- Section 5 concludes this report.

2. The Survey

2.1 Selecting the Sample

The NHIA provided Abt Associates with a membership list of organizations providing home infusion therapy services. This list was divided into the following groups of providers:

- National providers – five large national providers; and
- Other providers – all other providers who were divided into five mutually exclusive geographic groups:
  - Providers located in rural (outside of metropolitan statistical areas) areas; and
  - Urban (MSA) providers, who in turn were organized into four geographic regions:
    - Northeast;
    - Midwest;
    - South; and
    - West.

The five national providers agreed to participate in the survey, and all five national organizations were selected as potential respondents. Other providers from each of the five geographic groups (rural, Urban Northeast, Urban Midwest, Urban South, and Urban West) were contacted at random and asked the following series of screening questions:

- Does your organization provide home infusion therapy services;
- Can your organization provide case mix information by S code – S codes are used by this study to define each per diem home infusion therapy service;
- Does your organization receive one half or more of its total gross revenues from home infusion therapy services; and
- Can your organization provide total costs for all services, nursing services, drugs and separately billed supplies, and per diem services?

Other providers responding positively to all four screening questions were then included in the study as potential respondents. The original intention was to screen in five providers from each of the other provider groups, but ultimately the following number of providers were screened in:

- Rural – four;
- Northeast – five;
- Midwest – five;
- South – eight; and
- West – six.

Thus, a total of 33 potential respondents – the five national providers and 28 other providers selected randomly – were included in the final sample.

2.2 Survey Instrument Development

A detailed survey instrument was created for this product that included questions in the following subject areas:

- Organization – in addition to the four screening questions, questions were asked regarding what states each provider offers home infusion services and how each provider would define themselves (e.g., serving patients in urban, rural, or both areas, or as independent, national, or hospital based providers);
- Case mix – total service volume by S code;
- Total costs and revenues – by type of service (nursing, drugs and separately billed supplies, and per diems), and for an organization's entire business and for infusion services provided in the home;
- Salary and fringe benefit data per employee for employees providing per diem services;
- Supply kit costs – the per diem costs, if any, for supplies included in the per diem service by S code;
- Pump and pump kit costs – the cost and useful life of various home infusion pumps and the per diem costs for associated pump kit supplies; and
- Average therapy length – the average length of therapy (in days), number of initial therapy setups and number of refills[15] typically provided in a normal course of therapy. In addition, respondents were asked to provide their delivery costs per service.

Instructions for completion and the complete Survey Instrument are included as Appendix C. Developing the survey instrument relied heavily on the NHIA Profitability Analysis Tool.[16]

2.3 Conducting the Survey

Each potential respondent was mailed a survey packet that included the following information:

- A survey instrument – in hard copy and in electronic form;
- A copy of the NHIA Quick Coding Reference for Home Infusion Therapy defining each S code service;
- An electronic copy of the NHIA Profitability Analysis Tool; and
- A set of survey instructions – including telephone and email contact information for the Abt project team.

The packets were mailed out in mid-April of 2005. Respondents were invited to participate in one or more conference calls the following week that discussed the project and explained the survey

[15] For the purposes of this survey, "refills" meant subsequent deliveries of drugs, supplies, and/or equipment during a typical course of therapy.

[16] The NHIA Profitability Analysis Tool is a spreadsheet model that is available to home infusion therapy providers to enter information on direct labor costs, supply costs, pump and pump kit costs, and service volumes, to assess their own financial performance and profitability. The review panel reviewed the NHIA Profitability Analysis Tool assumptions regarding labor times, and some labor time assumptions were updated as a result of that review.

instrument in more detail. Respondents were also guaranteed that their information would remain strictly confidential and would not be shared with any outside party, including NHIA.

Respondents were initially provided three weeks to respond to the survey, and could choose to respond: (1) by mailing back their completed hard copy survey forms; (2) by emailing an electronic version of their results; (3) by mailing back a CD ROM with their completed survey; or (4) by faxing back their responses. The survey period was ultimately extended an additional six weeks, allowing respondents up to nine weeks to respond to the survey. Some final information was received as late as mid July, 13 weeks after the survey was initially mailed out.

A survey instrument was developed and sent out in mid-April of 2005 to five national and 28 randomly selected other home infusion therapy providers. Ultimately, we received seven usable responses, including responses from all five national providers and two of the other randomly selected providers. Almost all of the responding providers (respondents) reported providing home infusion therapy services in more than one state and in aggregate the there were at least 179 home infusion therapy pharmacies. As a result, collectively the survey respondents provided home infusion therapy services in all 50 states and the District of Columbia. While most respondents provided information on their entire home infusion therapy operations, one respondent reported information separately for eight (8) of its subsidiary operations. Thus, the seven respondents provided 14 (six plus eight) surveys, providing information for the calendar year 2004 (January 1, 2004 to December 31, 2004). In summary:

- Survey respondents provided services in all 50 states and reported data encompassing the operations of at least 179 home infusion therapy pharmacies.

3. Methodology

Estimating the per diem costs for each S code were calculated in three steps:

- "Bottom up" costs were calculated for each S code and each provider;
- A "top down" adjustment was made to each provider's bottom up S code estimates to assure that the resulting estimates reflected each provider's total per diem cost estimates;
- Mean per diem cost estimates were then calculated across all providers responding to the survey for each code, where these means were weighted to adjust for the probability of being included in the sample and for each provider's size (as measured by the provider's total per diem costs).

Each of these three steps is described below.

3.1 Bottom Up Cost Estimates

For each S code, the direct per diem costs associated with the code were calculated as follows:

Direct Cost = Labor Cost + Supply Kit Cost + Pump and Pump Kit Cost + Delivery Cost.

The approach used to estimate each of the four types of "bottom up" direct costs is discussed in turn below.

Labor Costs

Home infusion therapy may last for extended periods of time. During each course of treatment, typically there is a single initial setup and delivery when the treatment first begins, followed by subsequent deliveries of new supplies of the drugs and any additional supplies, pump kit materials and/or equipment. These subsequent deliveries were called refills for survey purposes. In most cases, less labor is required for refills than for initial setups. Per diem labor costs during each course of home infusion treatment are the labor costs for the initial setup and refills, divided by the number of days of care.

The NHIA Profitability Analysis Tool provided minutes of care by labor category for initial setups and refills by S code. Minutes by each labor category were multiplied by the average cost (salary and fringe) per minute for that category of labor for each responding provider to estimate labor costs for each initial setup and each refill. Labor costs per minute were calculated assuming that a full time equivalent worked 1,896 hours per year.[17] For providers with one or more missing values for their labor costs, simple average labor costs per minute across all respondents were used.

We note that there are substantial patient-specific labor-intensive activities performed by home infusion pharmacy staff in between actual refill occurrences. Just a few examples would include review of lab results, consultation to physician, contact with patients to assess therapy status and

[17] Starting with 365 days per year, the following days were excluded: (1) weekends (104 days); (2) vacation (10 days); (3) holidays (eight days); and (4) sick time (six days). Assuming an eight-hour day, the remaining 237 days is equivalent to 1,896 hours (or 113,760 minutes).

future delivery requirements, 24/7 triage of patient calls, and billing and collection activities. The NHIA National Definition of Per Diem provides a thorough list of such activities (see Appendix B). While the designers of the NHIA Profitability Analysis Tool attempted to include such labor into the refill labor minutes, it is possible that the refill minutes do not consistently reflect this extra time and, consequently, part of the top down cost adjustments would reflect these activities.

The labor costs per initial setup and refill were then multiplied by the number of initial setups and refills to estimate total bottom up labor cost estimates for an entire normal period of therapy. The initial setup and refill labor costs were then added together and divided by the average length of therapy to estimate bottom up per diem labor cost estimates for each S code.

Several issues needed to be resolved to finalize the bottom up per diem labor cost estimates. First, the number of initial setups, refills, and average length of therapy by S code needed to be determined. While respondents were asked to provide these values in their survey responses, there was concern expressed by the review panel that survey respondents might have confused what an initial setup meant. For example, did some respondents believe each time the dosage, concentration, or length of infusion changed during a typical course of therapy reflects a "new" initial setup? It should be noted that some respondents provided an initial setup value of one for every code. To add consistency to the survey compilation, the review panel decided to assume one (1) initial setup for all S codes when bottom up per diem labor costs were being estimated. The number of refills and average length of therapy were assumed to be the simple, unweighted average of survey responses.

Second, the NHIA Profitability Analysis Tool did not provide labor minutes by labor category (for initial setups and refills) for all S codes. The review panel consulted with the designers of the NHIA Profitability Analysis Tool to determine labor minutes for all S codes.

Finally, most S code families include an unspecified code, and there are two not otherwise classified codes, one for infusion services (S9379) and one for injection services (S9542). While survey respondents were asked to provide average therapy lengths, initial setups, and refills for these codes, the unspecified and not otherwise classified codes are really meant to encompass all other codes in each code family. As a result, it was decided that the number of refills and average therapy lengths for these codes would equal the (volume) weighted average values of refills and average therapy lengths for all codes in each code family across all respondents. Similar volume weighted average values for all codes in each code value were used to determine supply kit, pump and pump kit costs for the unspecified and not otherwise classified codes.[18] Ultimately, it was determined with the review panel that due to the broad and diffuse services included in the two not otherwise classified codes, it wouldn't be appropriate to include the cost estimates for S9379 and S9542 in this report.

Supply Kit Costs

Respondents were asked to provide their per diem supply kit costs for each code. These values were used to estimate per diem supply kit costs. Providers that did not supply some or all supply kit cost data were assumed to have per diem supply kit costs equal to the unweighted average supply kit costs of all providers who provided these data.

[18] The code families for the not otherwise classified codes were all infusion codes (for not otherwise classified infusion) and all injectable codes (for not otherwise classified injection).

Pump and Pump Kit Costs

The NHIA Profitability Analysis Tool provided information on the type of pumps used for different codes; pumps are not used for all codes. For codes not included in the NHIA Profitability Analysis Tool, assumptions for similar codes on pump use were used. Pump costs were converted into per diem pump kit costs as follows. The pump's cost (acquisition cost for purchase, lease or rental cost for leased or rented pumps) was divided by the reported useful life (years of useful life times 365.25 days per year) for purchased pumps or by the lease or rental period to calculate per diem pump costs. To these costs, annual maintenance costs were added, after first converting these annual into per diem costs. The associated per diem pump kit costs were then added to estimate total per diem pump and pump kit costs. Unweighted, average per diem values for pump and pump kit costs were used for providers with missing values.

Delivery Costs

Each respondent's cost per delivery was multiplied by the number of initial setups and refills for each S code. This total delivery amount was then divided by the average length of therapy for each code, yielding a per diem delivery cost per code. Respondents who did not report delivery costs were assumed to have delivery costs per service equal to the unweighted average delivery cost per service across all respondents providing these data.

It is noted earlier that services necessary for home infusion therapy are notably different than those provided from traditional community retail pharmacies. As compared to much lower dispensing fees typically reimbursed to traditional community retail pharmacies for filling prescriptions, the average direct cost for the delivery component alone was found to be $38.25.[19] In addition to delivery, the many other incurred costs--referral processing, intake qualification and documentation setup, care coordination, verifying physician order set, sterile compounding, packaging, patient education, clinical monitoring, insurance administration, etc.—are reported in the per diem costs.

3.2 Top Down Cost Adjustments

The "bottom up" direct cost estimates per code in most cases probably underestimated the total per diem costs of providing these services for providers. That is because these estimates did not include other, indirect costs – other labor costs (e.g., for management staff), rent, etc.—and also not included may be patient-specific activities at times other than occurrences of refills as explained in Section 3.1.1. To assure that all costs, both the bottom up, direct costs and indirect costs are included as well as to validate the bottom up cost estimates, the following "top down" adjustments were made.

For each provider, the bottom up per diem cost estimates for each S code were multiplied by each S code's volume and then summed. The resulting summed products are the organization's total, bottom up direct costs. These total, bottom up direct costs were then compared to the total per diem costs (top down costs) reported by that organization for services provided in the home. The bottom up, direct cost estimates were then adjusted by a common factor – the ratio of top down costs (direct and indirect costs) to bottom up (direct only) costs – to assure that the final, top down per diem cost

[19] This "direct" average delivery cost does not include any (indirect) top-down adjustment (as described below). Home infusion therapy drugs and equipment often must be delivered to multiple, distant locations, as a opposed to a central "neighborhood" for a community pharmacy.

estimates capture all the organization's per diem costs. For example, suppose for provider A, total bottom up costs were $10,000,000 and total top down costs were $15,000,000. The ratio of these amounts -- $15,000,000/$10,000,000 = 1.50, was used to adjust each of the bottom up per diem cost estimates to the final top down amount. If the bottom up per diem cost for Code B was $100, the final, top down per diem cost estimate for that code would be $150.

The individual adjustment ratios varied from 1.10 to 2.34. For providers that did not report either the case mix or total per diem costs necessary to calculate a top down adjustment ratio, the cost and sample weighted (see Section 3.3 below) mean adjustment ratio, or 1.54, was used to adjust their bottom up per diem cost estimates into final, top down cost estimates.

3.3 Weights

The top down per diem cost estimates for each S code were then averaged across all 14 survey responses to arrive at final values for each S code. These means were weighted to adjust for two factors:

- Total costs – each response was weighted in proportion to its total per diem costs; and
- Sample weights – the probability of being selected into the survey was also used to adjust the final calculations. The "other" providers surveyed were weighted more heavily than the national providers, because the other providers were much less likely to be included in the final set of survey responses.

While we believe weighting yielded more accurate results, the effect of weighting on the per diem cost estimates was not that large and tended to reduce those estimates. Compared to simple, unweighted average per diem costs across the 14 survey responses, the weighted estimates were lower for 44 of the 59 S codes. The unweighted and weighted per diem estimates differed by less than 10 percent for 32 of the 59 codes.

4. Results

4.1 Provider Characteristics

Geographically, the survey had excellent geographic representation. As previously mentioned in Section 2.3 above, the seven respondents completed a total of 14 surveys (six providers completed one survey each, while a seventh provider completed eight surveys). The results reported in Exhibit 1 and Appendix D reflect the 14 completed surveys (survey sites).

All states except the District of Columbia and Hawaii were served by two or more survey sites, 12 states (California, Florida, Georgia, Kentucky, Minnesota, Missouri, Nevada, New York, Rhode Island, Virginia, West Virginia, and Wisconsin) were served by four survey sites, two (Illinois and Pennsylvania) by five sites, two (Michigan and Ohio) by six survey sites and one state (Indiana) was served by seven survey sites. The five national providers alone represented 177 home infusion therapy pharmacies. Complete information on the number of responding providers offering services in each state is contained in Appendix D.

There was also a good mix of respondent types (see Exhibit 1). Respondents provided services in both urban and rural areas, and while national providers were the most commonly reported organizational type, both independent and hospital-based organizations were represented.

Exhibit 1
How Respondents View Their Organizations

Screening Question	Number of Survey Sites	Number of Survey Sites "Yes" to Each Answer	Percentage of Survey Sites Responding "Yes" to Each Answer
Where does your organization provide home infusion services	14		
• Primarily in urban areas		4	29
• Primarily in rural areas		2	14
• In both urban and rural areas		8	57
Would you consider your organization to be:*	14		
• An independent provider		4	29
• A national provider		9	64
• A hospital-based provider		2	14

* *One survey site reported itself to be both an independent and a hospital-based provider.*

4.2 Per Diem Costs by S Code

Exhibit 2 presents the following information for each S code:

- S code number;
- Code description;
- Mean per diem cost – sample and cost weighted. Costs presented both in 2004 dollars (the year of the survey) and in 2005 dollars. The 2004 values were adjusted using the Consumer Price Index for Urban areas (CPI-U) for medical care from November, 2004 to November, 2005 to provide estimates in current year dollars; [20] and
- Coefficient of variation (c.v.) – this is the ratio of the unweighted standard deviation of per diem cost to the unweighted mean per diem cost across all 12 respondents. Coefficients of variation in excess of 1.00 are indicative of high cost variability for a given S code.

To be consistent with per diem coding methodology, this study provided estimates of the costs of each per diem service for each day of therapy during an average period of therapy. However, there are some services, especially those for which administration of the drugs is infrequent over an extended course of therapy, where some payers provide payment only for the day or days the drugs are administered. For these codes, Exhibit Two provides estimates per drug administration day (in

[20] To present these home infusion therapy service per diem cost estimates in current year dollars, adjusting the costs each year using the change in the CPI-U for medical services would be warranted.

both 2004 and 2005 dollars). Per diem costs would depend upon a provider's assumption/experience with average total lengths of therapy for these codes.

One of the most striking general findings from Exhibit 2 is the extreme variability in the mean per diem cost estimates. Even within families of codes, the mean per diem costs varied widely, as demonstrated by the family of anti-infective codes at the top of Exhibit 2. These wide variations in mean per diem costs highlight the importance of having a full range of codes to define each per diem service.

The other striking finding was the low level of variation in costs across respondents for any given code. The coefficient of variation statistics ranged from 0.20 to 0.52 – i.e., every S code's c.v. was less than 1.00. In addition, there was no evidence that codes with lower volumes had higher variability across the respondents – the simple correlation between the coefficients of variation and service volumes per code was mildly positive (0.15), indicating a very weak tendency for higher volume codes to have greater coefficients of variation.[21]

[21] Admittedly, lower mean cost variability for lower volume codes in part may be due to the greater likelihood that some imputed data were used to calculate the per diem cost estimates for each responding provider.

Exhibit Two
Total Per Diem Cost Estimates by S Code

S Code		Mean Per Diem Cost	Mean Per Diem Cost Adjusted to 2005 Using CPI-U	C.V.	Mean Cost Per Drug Administration Day*	Mean Cost Per Drug Administration Day* Adjusted to 2005 Using Medical Care CPI-U
Anti-Infectives: Antibiotics, Antifungals, Antivirals						
S9497	Q3 Hours	$102	$107	0.34		
S9504	Q4 hour3	$100	$104	0.33		
S9503	Q6 Hours	$94	$98	0.32		
S9502	Q8 Hours	$77	$81	0.27		
S9501	Q12 Hours	$77	$80	0.26		
S9500	Q24 Hours	$70	$73	0.27		
S9494	Unspecified	$76	$79	0.27		
Chemotherapy						
S9330	Continuous (>= 24 Hours)	$142	$148	0.31		
S9331	Intermittent (< 24 Hours)	$175	$183	0.24		
S9329	Unspecified	$143	$150	0.30		
Enteral Nutrition						
S9343	Bolus	$15	$16	0.33		
S9341	Gravity	$18	$18	0.25		
S9342	Pump	$34	$36	0.48		
S9340	Unspecified	$30	$31	0.46		
Hydration Therapy						
S9374	1.0 Liter/Day	$88	$92	0.30		
S9375	>1.0-2.0 Liters/Day	$92	$96	0.31		
S9376	>2.0-3.0 Liters/Day	$92	$96	0.31		
S9377	>3.0 Liters/Day	$92	$96	0.31		
S9373	Unspecified	$90	$94	0.30		
Pain Management						
S9326	Continuous (>= 24 Hours)	$87	$91	0.36		
S9327	Intermittent (< 24 Hours)	$86	$90	0.27		
S9328	Implanted Pump*			0.26	$326	$341
S9325	Unspecified	$86	$89	0.34		

The Review Panel determined that there were a limited set of services that are provided infrequently over extended periods. For these codes, instead of calculating per diem costs, costs per administration day were calculated instead. Per diem costs would equal the per administration costs divided by the number of days between each drug administration, and that number of days could vary across providers.

Exhibit Two (continued)
Total Per Diem Cost Estimates by S Code

S Code		Mean Per Diem Cost	Mean Per Diem Cost Adjusted to 2005 Using CPI-U	C.V.	Mean Cost Per Drug Admini-Stration Day*	Mean Cost Per Drug Admini-stration Day* Adjusted to 2005 Using Medical Care CPI-U
Catheter Care and Maintenance						
S5498	Single Lumen	$24	$26	0.26		
S5501	>1 Lumen	$28	$29	0.26		
S5502	Implanted Access*			0.28	$197	$206
S5497	Unspecified	$26	$27	0.27		
Specialty Therapies: Infusion						
S9336	Anticoagulant Cont. Infusion	$102	$107	0.37		
S9351	Anti-emetic Cont. Infusion	$88	$92	0.39		
S9345	Anti-Hemophiliac Agent Inf.*			0.30	$284	$297
S9359	Anti-Tumor Necrosis Factor Intravenous Infusion*			0.23	$446	$466
S9355	Chelation Infusion	$69	$72	0.42		
S9490	Corticosteriod Infusion	$162	$170	0.26		
S9361	Diuretic Intravenous Inf.	$68	$71	0.26		
S9357	Enzyme Replacement Intravenous Infusion*			0.24	$453	$474
S9338	Immunotherapy Infusion*			0.27	$554	$578
S9348	Inotropic/Sympathomimetic Infusion	$89	$93	0.37		
S9353	Insulin Continuous Infusion	$62	$65	0.52		
S9349	Tocolytic – Infusion	$63	$66	0.51		
S9347	Uninterrupted, Long-term Controlled Rate Intravenous or Subcutaneous Infusion	$147	$153	0.29		
Specialty Therapies: Injection						
S9372	Anticoagulant Intermittent Injection	$54	$56	0.27		
S9370	Anti-Emetic Intermittent Injection	$51	$53	0.29		
S9558	Growth Hormone Injectable	$27	$29	0.25		
S9537	Hematopoietic Hormone Inj.	$57	$59	0.26		
S9560	Hormonal Injection	$24	$25	0.26		
S9559	Interferon Injection	$40	$42	0.27		
S9562	Palivizumab Injectable*			0.26	$281	$293

The Review Panel determined that there were a limited set of services that are provided infrequently over extended periods. For these codes, instead of calculating per diem costs, costs per administration day were calculated instead. Per diem costs would equal the per administration costs divided by the number of days between each drug administration, and that number of days could vary across providers.

Exhibit Two (continued)
Total Per Diem Cost Estimates by S Code

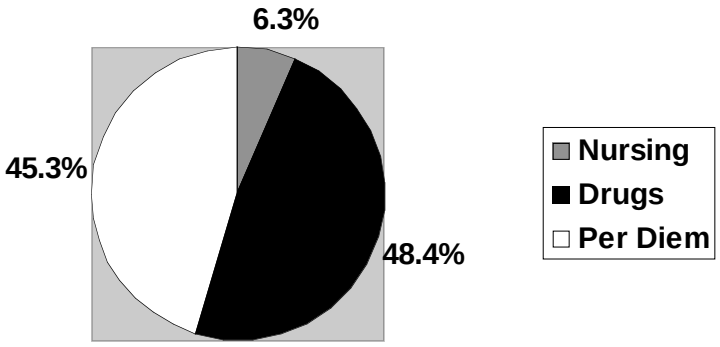
S Code		Mean Per Diem Cost	Mean Per Diem Cost Adjusted to 2005 Using CPI-U	C.V.	Mean Cost Per Drug Administration*	Mean Cost Per Drug Administration Day* Adjusted to 2005 Using Medical Care CPI-U
Specialty Therapies: Other						
S9061	Aerolized Drug	$22	$23	0.42		
S9363	Anti-Spasmodic Inf.*			0.25	$272	$284
S9590	Irrigation Inj.	$23	$24	0.26		
High Tech Nursing Service Coded and Paid Separately						
S5522	PICC Line Insertion	$142	$149	0.33		
S5520	PICC Line Kit	$235	$246	0.30		
S5523	Midline Insertion	$142	$149	0.34		
S5521	Midline Kit	$250	$261	0.29		
S5517	Declot Supply Kit	$190	$198	0.27		
S5518	Repair Supply Kit	$205	$214	0.25		
Extra Services						
S9470	Nutritional Counseling, Dietician Visit	$248	$259	0.20		

The Review Panel determined that there were a limited set of services that are provided infrequently over extended periods. For these codes, instead of calculating per diem costs, costs per administration day were calculated instead. Per diem costs would equal the per administration costs divided by the number of days between each drug administration, and that number of days could vary across providers.

4.3 Other Results

Respondents also were asked to report their total costs for nursing, drugs, and per diem services. Shares of total costs for those who responded were as follows in 2004:

Percentage of Home Infusion Therapy Costs: Nursing, Drugs, and Per Diem For Responding Providers



These cost shares demonstrate that home infusion therapy pharmacies provide products and service well beyond just the drugs, including home infusion nursing and everything captured within per diem reporting. Other survey results included the following:

- Nursing cost per visit -- $128[22]
- Delivery cost per service -- $38[23]

[22] Nursing costs per visit were calculated by dividing reported home infusion nursing costs by nursing visits and may not include any top-down adjustment for overhead and indirect costs.

[23] This "direct" average delivery cost does not include any top-down adjustment for overhead and indirect costs.

5. Conclusions

There were three strong findings for the resulting per diem cost estimates:

- Mean per diem costs varied greatly across codes, even within therapy code families, strongly indicating the importance of using a comprehensive series of S codes to define different home infusion services.
- There was very little variation in the cost estimates for each code across providers – the unweighted coefficients of variation (c.v.) across the 14 respondents varied from 0.18 to 0.51 – cost variation usually is not considered to be a significant problem unless c.v.'s exceed 1.00.[24]
- It is noted earlier that services necessary for home infusion therapy are notably different than those provided from traditional community retail pharmacies. As compared to much lower dispensing fees typically reimbursed to traditional community retail pharmacies for filling prescriptions, the average direct cost for the delivery component alone was found to be $38.25.[25] In addition to delivery, the many other incurred costs--referral processing, intake qualification and documentation setup, care coordination, verifying physician order set, sterile compounding, packaging, patient education, clinical monitoring, insurance administration, etc.—are reported in the per diem costs.

In addition, the cost shares presented in Section 4.3 demonstrate that home infusion therapy pharmacies provide to their patients not only drugs but also often home infusion nursing, and especially the services and products reported in the per diem S codes.

This study was the first attempt to estimate home infusion per diem costs for each service (S code) and may help educate both providers and payers on the resource costs required for provision of home infusion therapies. As previously mentioned, however, home infusion therapy pharmacies also provide drugs and often nursing services to their clients. Future, more comprehensive cost studies should analyze drug and nursing cost measures to complement this study of per diem costs, to offer a more complete picture of the total costs to safely and effectively provide quality home infusion therapy services.

[24] The coefficient of variation is the ratio of the standard deviation to the mean per diem cost.

[25] This "direct" average delivery cost does not include any (indirect) top-down adjustment. Home infusion therapy drugs and equipment often must be delivered to multiple, distant locations, as a opposed to a central "neighborhood" for a community pharmacy.

Appendix A: National Accreditation Organizations' Requirements for Provision of Home Infusion Therapy

NHIA provided Abt Associates with statements of the requirements for provision of home infusion therapy from each of the three national organizations that accredit home infusion therapy pharmacies:

- Accreditation Commission for Health Care (ACHC)
- Community Health Accreditation Program (CHAP)
- Joint Commission for Accreditation of Healthcare Organizations (JCAHO

Accreditation Commission
for Health Care, Inc. *Est. 1986*

Dear Sir or Madam:

As our nation continues to struggle with health care cost pressures, the question of how to ensure health care quality in the context of cost management is of significant concern to all. In this context, accreditation has performed an important function in validating providers' adherence to nationally accepted standards.

The Accreditation Commission for Health Care, Inc. supports the position of the National Home Infusion Association that home infusion pharmacy organizations must be held to the highest professional standards of practice. ACHC accreditation standards are developed to assure the continuous and ongoing provision of quality infusion services and ensure patient safety, drug regimen compliance, and achievement of therapeutic goals. Our standards, criterion, and interpretations are comprehensive, thorough, and explicit in expectations. Compliance with these standards requires commitment of staff, time, and financial resources. To meet ACHC standards, home infusion pharmacy organizations must:

- Document that credentialing activities are conducted at the time of hiring and annually, and that ongoing education and training are provided to maintain competency. Verification of license is conducted on all referring physicians and others authorized by law to prescribe therapy and medications.
- Have written admission policies that include patient participation in writing the plan of care, patient education, emergency procedures and service availability 24 hours a day, 7 days a week.
- Have a client care coordinator/case manager for each patient with the plan of care activities coordinated with other community providers and physicians.
- Conduct a systematic and comprehensive initial assessment, with periodic reassessments that include patient history, physical and medical condition, cognitive and psychosocial state, appropriate treatment protocols, medication review, and method of drug administration.
- Document that service delivery is communicated with all clinicians involved with the patient. Case conferences should include therapy progress and any complications.
- Demonstrate that the pharmacy stores pharmaceuticals and equipment under appropriate conditions of security, sanitation, light and temperature in accordance with local, state, federal and Board of Pharmacy requirements.
- Demonstrate that sterile infusion products are compounded in a Class 100 environment using the appropriate compounding equipment. Laminar flow hoods are certified annually or in accordance with state Board of Pharmacy regulations.
- Monitor potential adverse drug reactions and incompatible administrative devices.
- Conduct quality improvement activities, which include description of indicators, frequency of activities, person responsible, methods of data collection, acceptable limits for findings, and corrective action plans.

Sincerely,

Thomas E Cesar

Thomas E. Cesar, MPM
President/CEO

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CHAP
COMMUNITY HEALTH ACCREDITATION PROGRAM
39 Broadway Suite 710 New York, NY 10006 tel: 212-480-8828 fax: 212-480-8832 web: www.chapinc.org

May 22, 2003

Dear Sir or Madam:

The Community Health Accreditation Program, Inc. (CHAP) accredits community based services/programs, including home infusion pharmacies. CHAP has written this informational letter in coordination with the National Home Infusion Association to provide your organization with information about accreditation standards, their role in the provision of services by home infusion providers, and the impact of the standards on providers' business environment.

CHAP's accreditation program strives to assure that patients receive quality-driven clinical services from the home infusion pharmacy. CHAP's accreditation standards are developed to assure the continuous and ongoing provision of quality infusion services, as well as the prevention and detection of such critical incidences as adverse drug reactions, medication errors, mechanical equipment failures, and patient/family non-compliance.

We applaud your organization's decision to require accreditation. Our hope is that you will recognize that the compliance with accreditation standards requires a commitment of staff, time, and financial resources.

In order to meet CHAP's standards, the pharmacy must provide a full spectrum of assessment, care planning, reassessment, and performance improvement activities.

Infusion pharmacies must:

- provide comprehensive assessment activities that consider patient history, current physical and medical status, laboratory reports, cognitive and psychosocial status, family/care partner support, prescribed treatment, and concurrent oral prescription and over the counter medications;
- perform drug/drug interaction monitoring and the identification of potential drug, dose, or drug-catheter incompatibilities
- provide comprehensive admission procedures that include patient teaching for mechanical and disposable equipment use, medication storage and handling, emergency procedures (i.e. natural or other disasters and emergencies), vascular access device management, recognition and reporting of adverse drug reactions and other infusion related complications;
- provide comprehensive care planning activities that consider actual or potential drug or equipment related problems, therapy monitoring with patient specific goals, coordination of activities with other providers such as home care agencies and physician offices;
- provide ongoing patient monitoring and reassessment activities to continually assess for response to treatment, drug complications, adverse reactions, and patient compliance;
- provide, as applicable, the review of patient laboratory finding, and consultation with the physician to adjust the medication orders in response to those results;

- provide, as applicable, the review of patient laboratory finding, and consultation with the physician to adjust the medication orders in response to those results;
- communicate, as applicable, with the home care agency on issues related to equipment, supplies, response to therapy, and complications;
- maintain appropriate physical facilities for the storage, preparation, dispensing, and quality control of all infusion medications and equipment in accordance with local, state, federal, and Board of Pharmacy regulations (which can be more extensive than requirements for "retail" pharmacies);
- maintain appropriate procedures for the compounding and distribution of sterile infusion products as described in national standards, federal and state regulations, and assure the continual quality control practices recommended by these organizations and other professional advisory organizations (which are more extensive than requirements for "retail pharmacies);
- maintain an ongoing employee education and competence validation program for all aspects of job functions;
- implement a comprehensive performance improvement program (i.e. quality management program) that includes the ongoing collection of clinical outcome data, patient perception data, the trending and analysis of these and other performance measure data, the root cause evaluation of all sentinel events, and the ongoing documentation of staff activities that use the data towards ongoing program improvement

Sincerely,

Terry A. Duncombe, RN, MSHA
President/CEO

Facts About
JCAHO Home Infusion Pharmacy Accreditation

JCAHO's home infusion pharmacy standards were developed to:

- Assure the continuous provision of quality infusion services
- Prevent and detect critical incidences such as adverse drug reactions, medication, errors, mechanical equipment failures, patient/family noncompliance

To meet JCAHO's home infusion pharmacy standards, a pharmacy must provide a full spectrum assessment, care planning, reassessment and performance improvement activities including:

- Comprehensive assessment activities that consider patient history, current physical and medical status, lab reports, cognitive and psychosocial status, family/care partner support, prescribed treatment, concurrent oral prescriptions and over the counter medications
- Drug interaction monitoring and identification of potential drug, dose or drug-catheter incompatibilities
- Comprehensive admission procedures that include patient education of medical and disposable equipment use, medication storage and handling, emergency procedures, vascular access device management, recognition and reporting of adverse drug reactions
- Comprehensive care planning that consider actual or potential drug or equipment related problems, therapy monitoring with specific patient goals, coordination of activities with other providers such as home health agencies and physician offices
- Ongoing patient monitoring and reassessment activities to continually assess for response to treatment, drug complications, adverse reactions, and patient compliance
- Laboratory report reviews, as applicable, and subsequent consults with appropriate care professionals to adjust medication orders as/if necessary
- Maintain appropriate physical facilities for storage, preparation, dispensing and quality control of all infusion medications and equipment
- Maintain appropriate procedures for the compounding and distribution of sterile infusion products as described in the national standards, federal and state regulations
- Maintain an ongoing employee education and competence validation program
- PI programs that include ongoing collection of clinical outcome data, patient perception data, trending and analysis of these and other performance measurement data, root cause evaluations of all sentinel events

For additional information about JCAHO's home infusion pharmacy accreditation, contact:

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JCAHO Home Care Accreditation
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Appendix B: National Definition of Per Diem

National Home Infusion Association
National Definition of Per Diem
June 2005

I. **Executive Summary**. The standardization of pertinent and relevant definitions is inherently advantageous to all stakeholders within the health care delivery system. Such standardization reduces the chance of differing expectations amongst stakeholders, encourages benchmarking and analysis that is based upon comparable data sets, and generally fosters communication and cooperation between the various entities responsible for providing medically necessary health care services. With infusion therapy, reimbursement is often based upon a per diem approach, yet frequently this term is left undefined. Accordingly, as the national organization representing infusion services, the National Home Infusion Association (NHIA) presents the following definition of the term "per diem."

II. **Per Diem Definition**. As related to reimbursement, the term "per diem" represents each day that a given patient is provided access to a prescribed therapy, beginning with the day the therapy is initiated and ending with the day the therapy is permanently discontinued. The term "permanently" shall not be construed to infer that a therapy shall never again be initiated, but rather that continuation of the therapy is simply not predicted or anticipated at the time of cessation. The expected course and duration of the treatment shall be determined by the plan of care as prescribed by the ordering physician.

It shall not be necessary for the patient to receive an actual drug infusion each and every day in order to be considered covered under an existing per diem, so long as additional infusions are anticipated in the near future as prescribed in the physician plan of care. The fact that the health care provider anticipates continued responsibility for the patient and incurs costs related to such responsibilities, remains accountable for the provision of such anticipated care, and is responsible for the acquisition and allocation of resources that will be necessary to meet these obligations, shall deem the existing per diem to be current, valid, and in force.

This definition is valid for per diem therapies of duration of up to and including every 72 hours. Therapies provided beyond this range (weekly, monthly, etc.) fall outside of the per diem structure, and should have separate reimbursement rates that are specified on a contractual or other basis.

III. **Examples:** For purpose of demonstration, the following examples are provided:

Prescribed Therapy	Units of Service
Infusion every 4 hours for 14 days	14
Infusion every 8 hours for 14 days	14

Infusion every 8 hours for 14 days	14
Infusion every 12 hours for 14 days	14
Infusion every 24 hours for 14 days	14
Infusion every 48 hours for 14 days	14
Infusion every 72 hours for 14 days	14
Infusion once per week	1 (per week)
Infusion once per month	1 (per month)

IV. **Cost Reconciliation.** Costs associated with therapies that are of a more infrequent nature (72 hours, 48 hours, etc.) are less than those that are more frequent, and decreased reimbursement for such services is thereby appropriate. Using the above as an example, it is expected that the "Every 72 hours" per diem would be reimbursed at lesser daily rate than the "Every 4 hours" per diem, and that the units of service would remain identical.

V. **Products and Services Included in the Definition.** Per diem reimbursement is intended to compensate for costs plus a fair return, i.e. the excess of revenues over expenses needed to ensure continued access to these therapies, for the following services, products and other support costs of an infusion therapy provider:

1. **Professional Pharmacy Services**

a. **Dispensing**

Medication profile set-up and drug utilization review

Monitoring for potential drug interactions

Sterile procedures including intravenous admixtures, clean room upkeep, vertical and horizontal laminar flow hood certification, and all other biomedical procedures necessary for a safe environment

Compounding of medications

Patient counseling as required under OBRA 1990

b. **Clinical Monitoring**

Development and implementation of pharmaceutical care plans

Pharmacokinetic dosing

Review and interpretation of patient test results

Recommending dosage or medication changes based

on clinical findings

Initial and ongoing pharmacy patient assessment and clinical monitoring

Measurement of field nursing competency with subsequent education and training

Other professional and cognitive services as needed to clinically manage the patient pharmacy care

c. **Care Coordination**

Patient admittance services, including communication with other medical professionals, patient assessment, and opening of the medical record

Patient/caregiver educational activities, including providing training and patient education materials

Clinical coordination of infusion services care with physicians, nurses, patients, patient's family, other providers, caregivers and case managers

Clinical coordination of non-infusion related services

Patient discharge services, including communication with other medical professionals and closing of the medical record

24 hours/day, 7 days/week availability for questions and/or problems of a dedicated infusion team consisting of pharmacist(s), nurse(s) and all other medical professionals responsible for clinical response, problem solving, trouble shooting, question answering, and other professional duties from pharmacy staff that do not require a patient visit

Development and monitoring of nursing care plans

Coordination, education, training and management of field nursing staff (or sub-contracted agencies)

Delivery of medication, supplies and equipment to patient's home

d. **Supplies and Equipment**

DME (pumps, poles and accessories) for drug and nutrition administration

Equipment maintenance and repair (excluding patient

owned equipment)

Short peripheral vascular access devices

Needles, gauze, non-implanted sterile tubing, catheters, dressing kits and other necessary supplies for the sale and effective administration of infusion, specialty drug and nutrition therapies

e. **Multiple Categories of Pharmacy Professional Services**

Maintaining comprehensive knowledge of vascular access systems

Continuing education to professional pharmacy staff

Removal, storage and disposal of infectious waste

Maintaining accreditation, including:

Outcomes assessments and analysis

Ongoing staff development and competency assessment

Continuous quality assessment and performance improvement programs

All other policies and procedures necessary to remain in compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Community Health Accreditation Program (CHAP), Accreditation Commission for HealthCare (ACHC), and other professional accreditation standards

Certification fees and expenses

Other applicable accreditation expenses

Maintaining the substantial insurance requirements (e.g. liability), including compliance with all state and federal regulations related to minimal insurance coverage

2. **Administrative Services**

Administering coordination of benefits with other insurers

Determining insurance coverage, including coverage for compliance with all state and federal regulations

Verification of insurance eligibility and extent of coverage

Obtaining certificate of medical necessity and other medical necessity documentation

Obtaining prior authorizations

Performing billing functions

Performing account collection activities

Internal and external auditing and other regulatory compliance activities

Retrieval and storage of medical and reimbursement records

Maintaining inventories of drugs, equipment, administration supplies and office supplies

Maintaining physical plant and offices, including building, equipment and furnishings, utilities, telephone, pagers, office supplies, etc.

Maintaining computer clinical and administrative information systems

Postage and shipping

Design and production of patient education materials

Quality assessment and improvement activities

Continuing education to administrative staff

Legal and accounting services

Licensing application activities and fees

3. **Other Support Costs**

Wages, salaries, benefits, payroll taxes, FICA, unemployment insurance, and workers compensation premiums

Property taxes

Asset depreciation

Inventory carrying costs

Accounts receivable carrying costs associated with carrying of large accounts receivable balances

Costs of insurance coverage per state regulations

Costs of maintaining accreditation (JCAHO, CHAP, ACHC, etc.)

New product research and development

Sales, advertising, and marketing

Community commitment and charitable donations

Other applicable overhead and operational expenses

VI. Products and Services Not Included in the Definition of Per Diem

- All drugs*, biologicals, enteral formulae and blood products
- Nursing services provided directly to patients in their residences or other alternate sites
- Other services provided directly to patients in their residences or other alternate sites by provider's staff or representatives (e.g. dietician for nutritional counseling)
- PICC and Midline insertion procedures and associated supplies
- Surgically implanted central vascular access devices
- Invasively placed digestive tract access devices for enteral therapy, including G tubes, NG tubes, J tubes, etc.
- Services and products not considered part of the per diem compensation as may be agreed to by provider and payer (e.g. delivery to high risk areas with escort or extra protection, wound care supplies and devices for sites other than IV catheter insertion sites, etc.)
- Services and products that may be provided at request of the patient that are considered by provider to be not medically necessary and beyond the scope of inclusion in the per diem
- All services and products provided when not otherwise paid for through per diem coding for a therapy episode.

* Except that components which are part of a standard TPN formula are included in the per diem: (a) non-specialty amino acids (e.g., Aminosyn®, FreAmine®, Travasol®), (b) concentrated dextrose (e.g., D10, D20, D40, D50, D60, D70), (c) sterile water, (d) electrolytes (e.g., CaCl2, KCL, KPO4, MgSo4, NaAc, NaCl, NaPO4), (e) standard multi-trace element solutions (e.g., MTE4, MTE5, MTE7), and (f) standard multivitamin solutions (e.g., MVI-13). Excluded from per diem reimbursement and reimbursed separately

are other drugs associated with TPN therapy: (a) specialty amino acids for renal failure (e.g., Aminess®, Aminosyn-RF®, NephrAmine®, RenAmin®), (b) specialty amino acids for hepatic failure (e.g., HepatAmine®), (c) specialty amino acids for high stress conditions (e.g., Aminosyn-HBC®, BranchAmin®, FreAmine HBC®, Premasol®, TrophAmine®), (d) specialty amino acids with concentrations of 15% and above when medically necessary for fluid restricted patients (e.g., Aminosyn® 15%, Clinisol® 15%, Novamine® 15%, Prosol® 20%), (e) lipids (e.g., Intralipid®, Liposyn®), (f) added trace elements not from a standard multi-trace element solution (e.g. chromium, copper, iodine, manganese, selenium, zinc), (g) added vitamins not from a standard multivitamin solution (e.g. folic acid, vitamin C, vitamin K), and (h) products serving non-nutritional purposes (e.g., heparin, insulin, iron dextran, Pepcid®, Sandostatin®, Zofran®). (Please note: trade names are used to provide a definition of per diem that communicates well; however, use of trade names is not a product recommendation or comment on extent of use in practice.)

VII. **Summary**. As the national standardization of relevant and pertinent definitions is deemed inherently advantageous to all stakeholders; and as NHIA is the national organization representing infusion services and standards, it is hereby established that the preceding definition of the phrase "per diem" is the national standard for purposes associated with infusion therapy reimbursement.

(Please note changes from June 2003 version marked in red font.)

THE NATIONAL HOME INFUSION ASSOCIATION

100 Daingerfield Road
Alexandria, Virginia 22314

Phone: 703.549.3740
Fax: 703.683.1484

Appendix C: Survey Instrument and Survey Instructions

The survey instrument used by this study and accompanying instructions begin on the next page of this Appendix C. As indicated in these documents, all survey responses were reviewed solely by Abt Associates Inc. Only findings of the study resulting from aggregated data were submitted to the review panel. The review panel, comprised of home infusion therapy providers, also reviewed and provided input on survey methodology.

Organizational Questions

Please confirm that the following information is correct regarding your organization:

	Yes	No
1. Your organization provides home infusion therapy services:		
2. Your organization will provide case mix information to this survey using S codes:		
3. Your organization receives half (1/2) or more if its total gross revenues from home infusion services (including nursing, drugs and other supplies separately billed from the per diem)?		
4. Your organization will be able to provide the following total cost information to this survey:		
4.a Total costs for all home infusion services:		
4.b Total costs for nursing services:		
4.c Total costs for drugs and separately billed supplies:		

5. Please provide the states (including the District of Columbia) where your organization provides home infusion therapy services (list all):

6. Does your organization provide home infusion therapy services in:

6.a Primarily urban areas		
6.b Primarily rural areas		
6.c Both rural and urban areas		

7. Would you consider your organization to be:

7.a An independent provider		
7.b A national provider		
7.c A hospital-based provider		

Case Mix

	Start Date	End Date
8. We request that below you provide your total volume of per diem home infusion therapy services for the entire calendar year 2004 (January 1, 2004 to December 31, 2004). If you are providing case mix data for a different period, please provide the beginning and end dates of the period you are reporting:		
9. What percentage of your organization's total home infusion service volume is billed using S codes (please provide your best estimate):		
10. What percentage of your organization's total home infusion service volume is provided in a home infusion therapy suite (please provide your best estimate):		

11. On the next four (4) pages below, we ask you to provide your organization's per diem home infusion therapy service volume by S code. For your convenience, we have included a description of each code or family of codes ("Description"), as well as provide additional summary information to distinguish codes or families of codes ("Q Hours or Summary").

Code	Description	Q Hours or Summary	Volume
S5497	Home Infusion Therapy, catheter care/maintenance, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC	
S5498	Same as S9457	Single lumen	
S5501	Same as S9457	> 1 lumen	
S5502	Same as S9457	Interim (implanted access device)	
S5517	Home infusion therapy, all supplies necessary for restoration of catheter potency or declotting	Catheter declotting supply kit	
S5518	Home infusion therapy, all supplies necessary for catheter repair	Catheter repair supply kit	
S5520	Home infusion therapy, all supplies (including catheter) necessary for a peripherally inserted venous catheter (PICC) line insertion	PICC line catheter kit	
S5521	Home infusion therapy, all supplies (including catheter) necessary for midline catheter insertion	Midline catheter kit	
S5522	Home infusion therapy, PICC insertion, nursing services only (no supplies or catheter included)	PICC line insertion w/o supplies	
S5523	Home infusion therapy, insertion of midline venous catheter, nursing services only (no supplies or catheter included)	Midline insertion w/o supplies	
S9061	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Aerosolized drug	
S9325	Home Infusion Therapy, pain management infusion, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC	
S9326	Same as S9325	Continuous	
S9327	Same as S9325	Intermittent	
S9328	Same as S9325	Implanted Pump	
S9329	Home Infusion Therapy, chemotherapy infusion, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC	
S9330	Same as S9329	Continuous	
S9331	Same as S9329	Intermittent	
S9336	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-coagulant continuous infusion	
S9338	Same as S9336	Immunotherapy infusion	

Code	Description	Q Hours or Summary	Volume
S9339	Same as S9336	Peritoneal dialysis	
S9340	Home Infusion Therapy, enteral nutrition, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (should be enteral)	NOC	
S9341	Home Infusion Therapy, enteral nutrition via gravity, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem	Gravity	
S9342	Home Infusion Therapy, enteral nutrition via pump, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem	Pump	
S9343	Home Infusion Therapy, enteral nutrition via bolus, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem	Bolus	
S9345	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-hemophilic agent infusion	
S9346	Same as S9345	Alpha-1 proteinase inhibitor	
S9347	Same as S9345	Uninterrupted, long term, controllable rate intravenous or subcutaneous infusion	
S9348	Same as S9345	Inotropic/sympathomimetic infusion	
S9349	Same as S9345	Tocolytic: infusion	
S9351	Same as S9345	Anti-emetic, continuous infusion	
S9353	Same as S9345	Insulin continuous infusion	
S9355	Same as S9345	Chelation infusion	

Code	Description	Q Hours or Summary	Volume
S9357	Same as S9345	Enzyme replacement intravenous infusion	
S9359	Same as S9345	Anti-tumor necrosis factor intravenous infusion	
S9361	Same as S9345	diuretic intravenous infusion	
S9363	Same as S9345	Anti-spasmodic infusion	
S9364	Home Infusion Therapy, total parenteral nutrition, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem	NOC	
S9365	Same as S9364	1 liter	
S9366	Same as S9364	1-2 liters	
S9367	Same as S9364	2-3 liters	
S9368	Same as S9364	3+ liters	
S9370	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-emetic, intermittent infusion	
S9372	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-coagulant intermittent injection	
S9373	Same as S9372	NOC	
S9374	Same as S9372	1 liter	
S9375	Same as S9372	1-2 liters	
S9376	Same as S9372	2-3 liters	
S9377	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	3+ liters	
S9379	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC Infusion Therapy per diem	
S9470	Nutritional counseling, dietician visit	Nutritional counseling	

Code	Description	Q Hours or Summary	Volume
S9490	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Corticosteriod infusion	
S9494	Home Infusion Therapy, antibiotic, antiviral, or antifungal therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC	
S9497	Same as S9494	3	
S9500	Same as S9494	24	
S9501	Same as S9494	12	
S9502	Same as S9494	8	
S9503	Same as S9494	6	
S9504	Same as S9494	4	
S9537	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Hematopoietic hormone injection	
S9538	Same as S9537	Blood product transfusion	
S9542	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC injectable therapy per diem	
S9558	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Growth hormone injectable	
S9559	Same as S9558	Interferon: injectable	
S9560	Same as S9558	Hormone injectable	
S9562	Same as S9558	Palivizumab injectable	
S9590	Same as S9558	Irrigation injectable	

Total Costs and Revenues

Please provide your total costs and revenues for the following home infusion services:

12. All Services (nursing, drugs and separately billed supplies, and per diem services):	All Services	Service Provided in the Home Only
12.a Total costs		
12.b Total revenues		
13. Nursing services		
13.a Total costs		
13.b Total revenues		
13.c Annual number of nursing visits		
14. Drugs and separately billed supplies		
14.a Total costs		
14.b Total revenues		
15. Per diem services		
15.a Total costs		
15.b Total revenues		

Salary and Fringe Benefits

16. Please provide the annual salary and fringe benefits for the following employee groups:

	Annual Salary	Annual Fringe	Total: Salary and Fringe
16.a Pharmacist			
16.b Pharmacist Tech			
16.c Warehouse Personnel			
16.d Infusion Nurse			
16.e Insurance Personnel			
16.f Other Administrative Personnel			

Pump and Pump Kit Costs

Next, we will ask you about three types of pumps -- ambulatory, stationary, and syringe pumps. For each pump type, we will ask if your organization typically purchases, rents or leases these pumps. For organizations that lease pumps, we will ask for your average purchase price and estimated useful life. For leasers, we ask for the total lease cost and lease period (e.g., 1/2 year, 1 year, 2 years, etc.). For renters, we ask for the rental cost per period and rental period (e.g., monthly, quarterly, yearly, etc.). In addition, we also ask you to estimate your annual maintenance costs per pump for each pump type.

17. Ambulatory Pumps

	Purchase	Lease	Rent
17.a Purchase, lease, or rent			

	Purchase Price	Useful Life	Maintenance Costs
17.b For purchasers:			

	Lease Cost	Lease Period	Maintenance Costs
17.c For leasers:			

	Rental Cost	Rental Period	Maintenance Costs
17.d For renters:			

18. Stationary Pumps

	Purchase	Lease	Rent
18.a Purchase, lease, or rent			

	Purchase Price	Useful Life	Maintenance Costs
18.b For purchasers:			

	Lease Cost	Lease Period	Maintenance Costs
18.c For leasers:			

	Rental Cost	Rental Period	Maintenance Costs
18.d For renters:			

19. Syringe Pumps

	Purchase	Lease	Rent
19.a Purchase, lease, or rent			

	Purchase Price	Useful Life	Maintenance Costs
19.b For purchasers:			

	Lease Cost	Lease Period	Maintenance Costs
19.c For leasers:			

	Rental Cost	Rental Period	Maintenance Costs
19.d For renters:			

20. Disposable pump costs -- please estimate your costs per pump for disposable pumps:

	Cost per Pump
20.a 100 ml	
20.b 200 ml	

21. Pump kit costs -- please estimate your costs per kit for the following pump kits: For convenience, the assumptions used by the NHIA Worksheet are provided.

	Cost per Kit
21.a Stationary pump tubing with filter	
21.b Ambulatory TPN pump	
21.c Ambulatory intermittent pump	
21.d Syringe pump tubing	
21.e Stationary pump without filter	

Supply Kit Costs

22. On the next three (3) pages below, we ask you to estimate your organization's per diem supply kit costs by S code. For your convenience, we have included a description of each code or family of codes ("Description"), as well as provide additional summary information to distinguish codes or families of codes ("Q Hours or Summary").

Code	Description	Q Hours or Summary	Estimated Cost per Day
S5497	Home Infusion Therapy, catheter care/maintenance, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC	
S5498	Same as S9457	Single lumen	
S5501	Same as S9457	> 1 lumen	
S5502	Same as S9457	Interim (implanted access device)	
S5517	Home infusion therapy, all supplies necessary for restoration of catheter potency or declotting	Catheter declotting supply kit	
S5518	Home infusion therapy, all supplies necessary for catheter repair	Catheter repair supply kit	
S5520	Home infusion therapy, all supplies (including catheter) necessary for a peripherally inserted venous catheter (PICC) line insertion	PICC line catheter kit	
S5521	Home infusion therapy, all supplies (including catheter) necessary for midline catheter insertion	Midline catheter kit	
S5522	Home infusion therapy, PICC insertion, nursing services only (no supplies or catheter included)	PICC line insertion w/o supplies	
S5523	Home infusion therapy, insertion of midline venous catheter, nursing services only (no supplies or catheter included)	Midline insertion w/o supplies	
S9061	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Aerosolized drug	
S9325	Home Infusion Therapy, pain management infusion, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC	
S9326	Same as S9325	Continuous	
S9327	Same as S9325	Intermittent	
S9328	Same as S9325	Implanted Pump	
S9329	Home Infusion Therapy, chemotherapy infusion, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC	

Code	Description	Q Hours or Summary	Estimated Cost per Day
S9330	Same as S9329	Continuous	
S9331	Same as S9329	Intermittent	
S9336	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-coagulant continuous infusion	
S9338	Same as S9336	Immunotherapy infusion	
S9339	Same as S9336	Peritoneal dialysis	
S9340	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC	
S9341	Home Infusion Therapy, enteral nutrition via gravity, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem	Gravity	
S9342	Home Infusion Therapy, enteral nutrition via pump, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem	Pump	
S9343	Home Infusion Therapy, enteral nutrition via bolus, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem	Bolus	
S9345	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-hemophilic agent infusion	
S9346	Same as S9345	Alpha-1 proteinase inhibitor	
S9347	Same as S9345	Uninterrupted, long term, controllable rate intravenous or subcutaneous infusion	
S9348	Same as S9345	Inotropic/sympathomimetic infusion	
S9349	Same as S9345	Tocolytic: infusion	
S9351	Same as S9345	Anti-emetic, continuous infusion	

Code	Description	Q Hours or Summary	Estimated Cost per Day
S9353	Same as S9345	Insulin continuous infusion	
S9355	Same as S9345	Chelation infusion	
S9357	Same as S9345	Enzyme replacement intravenous infusion	
S9359	Same as S9345	Anti-tumor necrosis factor intravenous infusion	
S9361	Same as S9345	diuretic intravenous infusion	
S9363	Same as S9345	Anti-spasmodic infusion	
S9364	Home Infusion Therapy, total parenteral nutrition, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing visits coded separately), per diem	NOC	
S9365	Same as S9364	1 liter	
S9366	Same as S9364	1-2 liters	
S9367	Same as S9364	2-3 liters	
S9368	Same as S9364	3+ liters	
S9370	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-emetic, intermittent infusion	
S9372	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-coagulant intermittent injection	
S9373	Same as S9372	NOC	
S9374	Same as S9372	1 liter	
S9375	Same as S9372	1-2 liters	
S9376	Same as S9372	2-3 liters	
S9377	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	3+ liters	
S9379	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC Infusion Therapy per diem	

Code	Description	Q Hours or Summary	Estimated Cost per Day
S9470	Nutritional counseling, dietician visit	Nutritional counseling	
S9490	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Corticosteriod infusion	
S9494	Home Infusion Therapy, antibiotic, antiviral, or antifungal therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC	
S9497	Same as S9494	3	
S9500	Same as S9494	24	
S9501	Same as S9494	12	
S9502	Same as S9494	8	
S9503	Same as S9494	6	
S9504	Same as S9494	4	
S9537	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Hematopoietic hormone injection	
S9538	Same as S9537	Blood product transfusion	
S9542	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC injectable therapy per diem	
S9558	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Growth hormone injectable	
S9559	Same as S9558	Interferon: injectable	
S9560	Same as S9558	Hormone injectable	
S9562	Same as S9558	Palivizumab injectable	
S9590	Same as S9558	Irrigation injectable	

Average Therapy Length

23 Please provide your average delivery charge per service:

24 Approximately what percentage of your home infusion therapy service volume is billed using total days of therapy (therapy days) and what percentage is billed using days where therapy is provided (reimbursable days)

Billed as Total Therapy Days	Billed as Reimbursable Days

25 The last part of the survey asks you to provide your average days when therapy is provided, number (#) of initial setups, and the number of times drugs are dispensed (# Dispensed) number of refills for each code. For average days of therapy, please report only the average number of days for which you receive payment.

Code	Description	Q Hours or Summary	Estimated Values		
			Average Days	# of Initial Setups	# Refills per Therapy
S5497	Home Infusion Therapy, catheter care/maintenance, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC			
S5498	Same as S9457	Single lumen			
S5501	Same as S9457	> 1 lumen			
S5502	Same as S9457	Interim (implanted access device)			
S5517	Home infusion therapy, all supplies necessary for restoration of catheter potency or declotting	Catheter declotting supply kit			
S5518	Home infusion therapy, all supplies necessary for catheter repair	Catheter repair supply kit			

Code	Description	Q Hours or Summary	Estimated Values		
			Average Days	# of Initial Setups	# Refills per Therapy
S5520	Home infusion therapy, all supplies (including catheter) necessary for a peripherally inserted venous catheter (PICC) line insertion	PICC line catheter kit			
S5521	Home infusion therapy, all supplies (including catheter) necessary for midline catheter insertion	Midline catheter kit			
S5522	Home infusion therapy, PICC insertion, nursing services only (no supplies or catheter included)	PICC line insertion w/o supplies			
S5523	Home infusion therapy, insertion of midline venous catheter, nursing services only (no supplies or catheter included)	Midline insertion w/o supplies			
S9061	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Aerosolized drug			
S9325	Home Infusion Therapy, pain management infusion, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC			
S9326	Same as S9325	Continuous			
S9327	Same as S9325	Intermittent			
S9328	Same as S9325	Implanted Pump			
S9329	Home Infusion Therapy, chemotherapy infusion, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC			
S9330	Same as S9329	Continuous			
S9331	Same as S9329	Intermittent			
S9336	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-coagulant continuous infusion			

Code	Description	Q Hours or Summary	Estimated Values		
			Average Days	# of Initial Setups	# Refills per Therapy
S9338	Same as S9336	Immunotherapy infusion			
S9339	Same as S9336	Peritoneal dialysis			
S9340	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC			
S9341	Home Infusion Therapy, enteral nutrition via gravity, administrative services, professional pharmacy services, care coordination, an all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem	Gravity			
S9342	Home Infusion Therapy, enteral nutrition via pump, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem	Pump			
S9343	Home Infusion Therapy, enteral nutrition via bolus, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem	Bolus			
S9345	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-hemophilic agent infusion			
S9346	Same as S9345	Alpha-1 proteinase inhibitor			
S9347	Same as S9345	Uninterrupted, long term, controllable rate intravenous or subcutaneous infusion			
S9348	Same as S9345	Inotropic/sympathomimetic infusion			
S9349	Same as S9345	Tocolytic: infusion			

Code	Description	Q Hours or Summary	Estimated Values		
			Average Days	# of Initial Setups	# Refills per Therapy
S9351	Same as S9345	Anti-emetic, continuous infusion			
S9353	Same as S9345	Insulin continuous infusion			
S9355	Same as S9345	Chelation infusion			
S9357	Same as S9345	Enzyme replacement intravenous infusion			
S9359	Same as S9345	Anti-tumor necrosis factor intravenous infusion			
S9361	Same as S9345	diuretic intravenous infusion			
S9363	Same as S9345	Anti-spasmodic infusion			
S9364	Home Infusion Therapy, total parenteral nutrition, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (lipids, specialty amino acid formulas, drugs other than in standard formula and nursing	NOC			
S9365	Same as S9364	1 liter			
S9366	Same as S9364	1-2 liters			
S9367	Same as S9364	2-3 liters			
S9368	Same as S9364	3+ liters			
S9370	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-emetic, intermittent infusion			
S9372	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Anti-coagulant intermittent injection			

Code	Description	Q Hours or Summary	Estimated Values		
			Average Days	# of Initial Setups	# Refills per Therapy
S9373	Same as S9372	NOC			
S9374	Same as S9372	1 liter			
S9375	Same as S9372	1-2 liters			
S9376	Same as S9372	2-3 liters			
S9377	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	3+ liters			
S9379	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC Infusion Therapy per diem			
S9470	Nutritional counseling, dietician visit	Nutritional counseling			
S9490	Home Infusion Therapy, hydration therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Corticosteriod infusion			
S9494	Home Infusion Therapy, antibiotic, antiviral, or antifungal therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC			
S9497	Same as S9494	3			
S9500	Same as S9494	24			
S9501	Same as S9494	12			
S9502	Same as S9494	8			

Code	Description	Q Hours or Summary	Estimated Values		
			Average Days	# of Initial Setups	# Refills per Therapy
S9503	Same as S9494	6			
S9504	Same as S9494	4			
S9537	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Hematopoietic hormone injection			
S9538	Same as S9537	Blood product transfusion			
S9542	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	NOC injectable therapy per diem			
S9558	Home Infusion Therapy, specialty therapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Growth hormone injectable			
S9559	Same as S9558	Interferon: injectable			
S9560	Same as S9558	Hormone injectable			
S9562	Same as S9558	Palivizumab injectable			
S9590	Same as S9558	Irrigation injectable			

NHIA Home Infusion Per Diem Cost Survey Instructions

Introduction and Overview

Thank you for agreeing to participate in the NHIA Home Infusion Per Diem Cost Survey. NHIA contracted with Abt Associates to conduct and then analyze the results of this survey to estimate the per diem costs (i.e., costs excluding nursing services in the home, drugs, and separately billed supplies) associated with providing home infusion therapy services. As indicated in the accompanying cover letter, all your responses to this survey will be strictly confidential and will not be reported to any outside parties. Any findings of the study will consist of aggregated results based on the data submitted by all respondents.

The survey package you have received should include the following materials:

- A cover letter from NHIA explaining the purpose of this study;
- A hard-copy set of survey instructions (this document);
- A hard-copy of the survey instrument;
- A copy of the NHIA Quick Reference for Home Infusion Therapy (laminated sheet);
- A self-addressed, stamped envelope for you to return the survey to us at the following address:

  Caity Baxter, Survey Data Coordinator
  Abt Associates, Inc.
  4550 Montgomery Avenue
  Suite 800 North
  Bethesda, MD 20814-3343

- A CD ROM with the following files:
  - Survey instructions (Survey Instructions.doc);
  - Survey instrument (Survey.xls);
  - A back-up copy of the survey instrument (Survey II.xls);
  - An example of a completed survey (Survey II Example.xls);
  - The NHIA Profitability Worksheet (NHIA Profitability Analysis Tool.xls); and
  - The NHIA Profitability Worksheet Instructions (NHIA Profitability Analysis Tool Directions.doc).

The example survey (Survey II Example) does not include any actual data; instead, it is provided to offer you an idea of how a completed survey might appear.

We have included electronic copies of the survey instrument for those who prefer responding to the survey in that way. If you prefer to fill-out the survey electronically, you can either return the CD ROM to us in the enclosed, self-addressed envelope, or email it to us at:

Katherine_Baxter@abtassoc.com

Kevin_Coleman@abtassoc.com

You may also send a facsimile copy of your completed survey to us (Attention: Caity Baxter) at (301) 634-1802.

If you have any questions regarding the survey, please either email us at the addresses provided above or call us at:

Katherine Baxter: (301) 634-1785

Kevin Coleman: (301) 634-1750

The deadline to respond to the survey is Friday, May 6, 2005.

Survey Instructions

The survey is organized into seven sections:

1. Organizational Questions – earlier, we contacted you by phone and asked a series of questions regarding your organization to screen you into this survey. We are asking these questions again to confirm this information or allow you to update your responses;
2. Case Mix – in addition to a few questions regarding your overall billing practices, we request that you provide your case mix volume by S code for Calendar Year (CY) 2004 (January 1, 2004, to December 31, 2004), or the most recent complete year of data you have available; and
3. Total Cost and Revenues – here, we ask you to provide your total costs and revenues for home therapy services – including nursing, drugs and separately billed supplies, and per diem services. While the focus of this study is on per diem costs, we are asking for information on other home infusion costs to make sure these are reflected accurately in our analysis.
4. Salary and Fringe Benefits – annual salary and fringe benefit costs for your home infusion therapy employees;
5. Pump and Pump Kit Costs – the costs associated with pumps and pump kits;
6. Supply Kit Costs – the costs associated with the supply kits used for each per diem home infusion therapy service (S code); and
7. Average Therapy Length – information on the average therapy length, doses per day, number of initial setups, and number of refills for each per diem home infusion therapy service (S code).

The last four sections (Sections 4 through 7) are derived from the NHIA Profitability Analysis Tool (NHIA Worksheet). As indicated above, we have included electronic copies of the NHIA Worksheet and directions for your convenience. The NHIA Worksheet was designed by NHIA to allow its members to determine whether particular reimbursement rate contracts for per diem home infusion therapy services would be profitable, given a member's cost structure and case mix. The NHIA Worksheet includes a number of formulas and assumptions regarding the costs and use of pumps, pump kits, supply kits, and labor that in turn are used to estimate the per diem costs of different S codes.

It is our intention to base much of our data analysis on the NHIA Worksheet. We would greatly appreciate it if you could also provide us with responses to all seven sections of the survey.). By doing so, our analysis will rely more completely on your organization's cost structure rather than on the assumptions now used by the NHIA Worksheet. If you cannot, please complete as much of the survey as possible – we are especially interested in the first three sections (Organizational Questions, Case Mix, and Total Costs and Revenues).

Organizational Questions

Question 1 is to confirm that your organization provides home infusion therapy services.

Question 2 is to assure that you can provide your case mix information using S codes. Complete S code descriptions are included in the NHIA National Coding Standard for Home Infusion Claims Under HIPAA, which can be found at:

http://www.nhianet.org/cgi-bin/Standards10501aReg.cfm

We have also included the NHIA Quick Reference for Home Infusion Therapy (the laminated sheet) for a more convenient reference to these codes.

Question 3 is designed to support one goal of the study -- to concentrate on organizations that primarily provide home infusion therapy services.

Question 4 confirms that you will be able to provide estimates of your total costs, nursing costs, and drugs and separately billed supply costs for home infusion therapy services. This will allow us to measure per diem home infusion therapy costs (i.e., Total costs – nursing costs – drugs and separately billed supply costs) in the survey.

A description of what costs are and are not currently included in per diem home infusion therapy services is provided in the Appendix to this document.

Question 5 asks you to provide in which state or states you presently provide home infusion therapy services.

Question 6 reflects another goal of the study – to include a mix of both urban and rural providers. By urban, we mean Metropolitan Statistical Areas (MSAs), where an MSA is defined as:

> *A geographic cluster of population defined by the United States Census Bureau. An MSA includes a city of at least 50,000 people or urbanized area of at least 100,000 people and the*

counties that include these areas.

Not all areas of the U.S. are in an MSA. There are over 300 regions of the country designated as MSAs. The remaining areas are identified by RSAs (Rural Service Areas). All counties in the country are within either an MSA or RSA. MSAs comprise 76% of the U.S. population, but only 22% of its land surface area.

A list of the 306 MSAs in the U.S. (as of November, 2004) can be found at:

http://www.census.gov/population/estimates/metro-city/List1.txt

Please use your own best judgment to answer this question.

Question 7 – one other goal of the study is to include a mix of provider organizational types. While there are no precise definitions, we ask you to self-identify your organization as:

- An independent provider – one that is not national or hospital-based;
- A national provider – an organization providing services in two or more regions of the country or five or more states; and
- A hospital-based provider – an organization owned or operated by a hospital or hospital chain.

Regions of the country include:

- North East:
  - New England – Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, and Connecticut;
  - Mid Atlantic – New York, New Jersey, and Pennsylvania;
- South
  - South Atlantic – Delaware, District of Columbia, Maryland, Virginia, West Virginia, North Carolina, South Carolina, Georgia, and Florida
  - East South Central – Kentucky, Tennessee, Mississippi, and Alabama;
  - West South Central – Oklahoma, Arkansas, Texas, and Louisiana;
- Mid West
  - East North Central – Michigan, Ohio, Indiana, Illinois, and Wisconsin;
  - West North Central – Minnesota, Iowa, Missouri, North Dakota, South Dakota, Nebraska, and Kansas; and
- West
  - Mountain – Montana, Wyoming, Colorado, New Mexico, Idaho, Utah, Arizona, and Nevada; and
  - Pacific – Alaska, Washington, Oregon, California, and Hawaii.

A map of the country's regions is available at:

http://www.census.gov/geo/www/us_regdiv.pdf

Case Mix

Question 8 asks for the beginning and end dates of the case mix data you are reporting if they differ from the requested period (CY 2004).

Question 9 asks for an estimate of the home infusion therapy service volume (in percentage) you currently bill using S codes – this question is for informational purposes.

Question 10 asks for an estimate of the amount of home infusion therapy services (in percentage) that you provide in home infusion therapy suites—this question again is informational.

Question 11 is a table asking you to provide your organization's service volume for per diem home infusion services by code. In addition to the S codes, there are also two other codes:

- 99601 – home infusion therapy/specialty drug administration, per visit (up to two hours) and
- 99602 – same as 99601 – except for each additional hour of administration.

For your convenience, we have provided descriptions of each code, including hours (frequency) or other summary information. For example, the specialty drug therapy codes, that summary information indicates the drug or therapy associated with each code.

Please provide your entire service volume for each code for an entire year (or for the period you are providing, if less than a full year). If you did not provide any services at all for a particular code, please enter a "0" as your volume for that code. It is quite likely that you may only provide services for a subset of the codes included in this survey.

Total Costs and Revenues

This section of the survey asks you to report your organization's total costs and revenues for home infusion therapy services. There are two columns – one for all home infusion therapy services provided in any setting, and a second column for those home infusion therapy services provided in patient homes. The categories include:

- Question 12 – all services – nursing provided in the home, drugs and separately billed supplies, and per diem services;
- Question 13 – nursing services;
- Question 14 – drugs and separately billed supplies; and
- Question 15 – per diem services.

As previously indicated, the Appendix provides a description of services that are and are not included in the per diem (essentially, the per diem includes all services except in-home nursing services, drugs and a few separately billed supplies).

Please note that we are asking you to provide your best estimates of both costs and revenues for each type of home infusion therapy service. The reason we are requesting both costs and revenues is to allow us to compare (in aggregate across all respondents), the costs and revenues – and thus margins – for each type of home infusion therapy service. In addition, we are also asking you to provide your total number of nursing visits, to allow us to calculate per visit nursing costs and revenues.

Salary and Fringe Benefits

Question 16 asks you to provide the annual salary, fringe benefit, and total (salary and fringe) costs associated with each of the following employee groups:

- Pharmacists;
- Pharmacist Tech;
- Warehouse Personnel;
- Insurance Personnel; and
- Other Administrative Personnel.

Salary information should include all paid annual compensation (i.e., salary, normal hourly wages, overtime wages, and annual bonuses).

Fringe benefits include worker compensation in addition to salary and wages and may include employer paid payroll and unemployment insurance taxes, health, life, and/or disability insurance, pensions (or stock ownership plans), and compensatory time off including vacation, holiday, and sick leave.

If you do not employ workers in one of these employee groups, please leave that question blank in the survey.

Pump and Pump Kit Costs

Questions 17 through 19 ask about the acquisition costs for three types of pump:

- Question 17 – ambulatory pumps;
- Question 18 – stationary pumps; and
- Question 19 – syringe pumps.

Questions include:

- Do you typically purchase, lease, or rent (a);
- For purchasers (b):
  - Purchase price (average purchase price – please provide your best estimate);
  - Useful life (in years); and
  - Annual maintenance costs (please provide your best estimate);
- For leasers (c):
  - Lease cost – for the period covered by the lease (please provide your best estimate);
  - Lease period – please indicate the lease period (e.g., ½ year, 1 year, 2 years, etc.); years); and
  - Annual maintenance costs (please provide your best estimate); and
- For renters (d):
  - Rental cost per period (please provide your best estimate);
  - Rental period (e.g., monthly, quarterly, yearly, etc.); and

- Annual maintenance costs (please provide your best estimate).

Question 20 asks you to provide your best estimate of the costs per pump of two (2) types of disposable pump:

- 100 ml pump (a); and
- 200 ml pump (b).

For your convenience, the NHIA Worksheet cost per day assumptions are provided.

Finally, Question 21 asks you for your best estimate of your costs per week for five types of pump kit:

- Stationary pump tubing with filter (a);
- Ambulatory total parenteral nutrition (TPN) pump (b);
- Ambulatory intermittent pump [c];
- Syringe pump tubing (d); and
- Stationary pump without filter.

If you do not use a particular pump or pump kit to provide services, please leave those questions blank in the survey.

Supply Kit Costs

Question 22 asks you to provide your best estimate of your supply kit costs per day (per diem) for each code.

If you do not provide a particular code or do not incur any supply kit costs for a code, please leave that question blank on the survey.

Average Therapy Length

Question 23 asks you to provide an estimate of the delivery cost you incur per service.

It is our understanding that payers (contracts) differ in how they reimburse for days of therapy in the home infusion therapy per diem. Some contracts allow you to bill for the entire period of therapy (therapy days), while other contracts only allow you to bill for those days in which drugs or other therapy is provided (reimbursable days). For example, antibiotics might be provided to a patient every second day during a 60-day period of care. In such an example, there would be 60 days of therapy and 30 reimbursable days of care. Question 24 then asks you to estimate what percentage of your home infusion therapy services are billed using all days of therapy and what percentage are billed using reimbursable days only.

Question 25 asks several questions about each code, including:

- Average days – please provide your estimate days for which you bill for services**;**

- Average doses per day;
- Number of initial setups (for an average course of treatment); and
- Number of times a drug is dispensed (for an average course of treatment).

Appendix D: Survey Sites by State

Number of Survey Sites Offering Home Infusion Services in Each State					
State	**N**	**State**	**N**	**State**	**N**
Alabama	2	Kentucky	4	North Dakota	2
Alaska	2	Louisiana	2	Ohio	6
Arizona	3	Maine	3	Oklahoma	2
Arkansas	2	Maryland	3	Oregon	3
California	4	Massachusetts	3	Pennsylvania	5
Colorado	3	Michigan	6	Rhode Island	4
Connecticut	2	Minnesota	4	South Carolina	2
Delaware	2	Mississippi	2	South Dakota	2
District of Columbia	1	Missouri	4	Tennessee	2
Florida	4	Montana	3	Texas	3
Georgia	4	Nebraska	3	Utah	3
Hawaii	1	Nevada	4	Vermont	2
Idaho	4	New Hampshire	3	Virginia	4
Illinois	5	New Jersey	3	Washington	3
Indiana	7	New Mexico	3	West Virginia	4
Iowa	3	New York	4	Wisconsin	4
Kansas	3	North Carolina	2	Wyoming	3

Survey results reflected data covering the operations of at least 179 home infusion therapy pharmacies providing services in all 50 states.

Appendix E: Review Panel

As mentioned in the body of this report, the NHIA convened an expert review panel to assist with all aspects of the survey and study. Review panel activities included:

- Approving the survey instrument and other survey materials used by this study;
- Reviewing the NHIA Profitability Analysis Tool, including providing labor minute values for codes missing these data as well as modifying other initial setup and refill labor minute values for other codes;
- Interpreting the study's per diem cost estimates – including deciding to set initial setups to one for all codes and using code family (volume weighted) average values for average therapy lengths, refills, supply kit, and pump and pump kit costs;
- Deciding which codes had problematic per diem cost estimates; and
- Providing edits and comments to this report that were considered and acted upon appropriately by Abt Associates.

One of the review panel activities is worthy of further explanation. After careful consideration, the review panel decided collectively that the per diem cost estimates for some S codes were problematic and they are not included in this report for the following reasons:

- Low service volumes – some codes were provided infrequently, often by only one or two providers;
- Total parenteral nutrition – the review panel determined that due to a flaw in the survey, parenteral formula costs were not being captured in the per diem cost estimates and for that reason, no per diem values are reported for parenteral nutrition; and
- Not otherwise classified codes (injection and infusion) – while the current S code per diem coding system includes unspecified codes for specific code families (e.g., for hydration therapy) and general not otherwise classified (NOC) codes for infusion and injection overall, correct coding practice should minimize the use of unspecified and especially NOC codes. After careful consideration, it was collectively determined that reporting cost estimates for unspecified codes was reasonable, as these codes encompass a limited and closely related set of services. In contrast, the large and varied services that the NOC injection and especially infusion codes may encompass were so broad and diffuse that it was decided not to report cost estimates for either NOC code.

The National Home Infusion Association (NHIA) contracted with Abt Associates, Inc. to conduct a survey and analysis of the per diem costs associated with providing home infusion therapy services. The report and this presentation material, written by Abt Associates, Inc., are made available for purchase by NHIA. Contact NHIA at (703)549-3740 or www.nhianet.org.

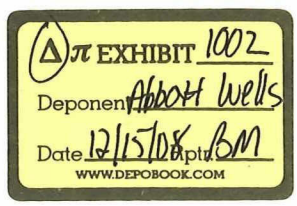
EXHIBIT 115

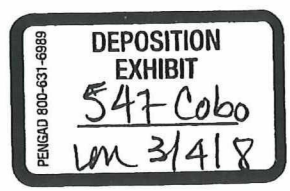
UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06-11337-PBS	)	(Original Complaint Filed in the Southern District of Florida, Case No. 06-21303-CIV-GOLD/TURNOFF)

THE UNITED STATES' FIRST AMENDED COMPLAINT

The United States brings this fraud action against Abbott Laboratories, Inc. ("Abbott") to recover losses sustained by the Medicare and Medicaid programs. Over the course of several years, Abbott reported inflated pharmaceutical prices that it knew Medicare and Medicaid relied upon to set reimbursement rates for Abbott's pharmaceutical products. Abbott's actual sales prices for its pharmaceutical products were far less than the prices reported by Abbott. By knowingly reporting inflated prices – often 1000% higher than Abbott's actual prices – Abbott ensured its customers received inflated reimbursement and profits from Medicare and Medicaid. Abbott then used the public fisc as a marketing tool, actively promoting government-funded "spreads" between (1) its fraudulently inflated prices and (2) its actual sales prices as an inducement to its customers. In addition, Abbott operated its own home infusion pharmacies and entered into profit-sharing partnerships with health care providers that allowed Abbott to directly profit off Abbott's manipulation of third party reimbursements for its drugs. These efforts allowed Abbott to increase its profits by boosting sales for its drugs.





I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and to recover damages and other monetary relief under the common law or equitable theories of fraud and unjust enrichment.

2. The United States bases its claims on Abbott having **submitted and** caused the submission of false or fraudulent claims to the United States in violation of 31 U.S.C. § 3729(a)(1), and having made and used false statements to get false or fraudulent claims paid by the United States in violation of 31 U.S.C. § 3729(a)(2).

3. Within the time frames detailed below, Abbott engaged in a fraudulent scheme that caused the Medicare and Medicaid programs to pay excessive reimbursement to Abbott's customers, *e.g.*, pharmacies, physicians, hospitals, home health agencies, nursing homes, home infusion companies, clinics and physicians (hereafter referred to collectively as "Customers"). In furtherance of this scheme, Abbott reported false, fraudulent and inflated drug prices for certain drugs (listed in ¶¶ 30 and 34 below) to several price reporting compendia that the Medicare and Medicaid programs relied upon to set reimbursement rates for Abbott's customers. A chart setting out examples showing the difference between the prices at which Abbott actually sold its drugs and the false prices reported by Abbott is attached hereto as **Exhibit 1**. Abbott knew that the Medicare and Medicaid programs relied on Abbott's reported prices to those compendia to set reimbursement rates for claims submitted for Abbott's drugs. Abbott then sold the drugs for far lower prices, and marketed to existing and potential Customers the government-funded

"spread" between the inflated reimbursement amounts and the actual acquisition costs of the drugs to boost its sales and profits.

4. Abbott knew that its false price reporting and marketing efforts would cause its Customers to submit claims for fraudulently inflated Medicaid and Medicare reimbursement.

5. Abbott's fraudulent scheme to induce Customers to purchase its products by ensuring that federal reimbursement rates for those products would be set at artificially inflated levels violated the FCA, the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), common law and numerous state laws.

6. To get fraudulent claims paid by the United States, Abbott also routinely made false statements directly to state Medicaid programs by reporting these same fraudulently inflated prices to the states. These statements violated the FCA, common law and various state laws.

7. The United States timely asserts the causes of action alleged herein based on the filing of relator's complaint in this action.

II. JURISDICTION

8. The United States' original Complaint in this matter was filed on March 16, 2006 in the Southern District of Florida.[1] The case was transferred to Multi-District Litigation ("MDL") No. 1456 on July 27, 2006. The Court has subject matter jurisdiction to entertain this action under 28 U.S.C. §§ 1331 and 1345 and supplemental jurisdiction to entertain the common law and equitable causes of action pursuant to 28 U.S.C. § 1367(a). The Court may exercise

[1] This case originated in the Southern District of Florida as Case No. 06-21303-CIV-GOLD/TURNOFF. The United States understands that this matter will be transferred back to the Southern District of Florida for trial upon the completion of these MDL proceedings.

personal jurisdiction over Abbott pursuant to 31 U.S.C. § 3732(a) because Abbott resides or transacts business in the District of Massachusetts.

III. VENUE

9. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Abbott resides or transacts business in this District.[2]

IV. PARTIES

10. The United States brings this action on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administer the Medicare and Medicaid programs.

11. Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), is a corporation organized under the laws of Florida, with its principal offices in Key West, Florida. Ven-A-Care is a pharmacy licensed to provide the prescription drugs specified in this Complaint and has been, during the relevant period of this Complaint, a Medicare and Florida Medicaid provider. Ven-A-Care's principal officers and directors have included John M. Lockwood, M.D., Zachary Bentley, Luis Cobo and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. The FCA, 31 U.S.C. § 3730(b)(1), provides that private parties may bring a lawsuit on behalf of the United States to recover damages for false claims. Ven-A-Care brought this action against Abbott on behalf of itself and the United States.

---

[2] Abbott also resides or transacts business in the Southern District of Florida as well. Thus, venue is also proper in that District.

12. Defendant Abbott is a corporation organized under the laws of Illinois with its principal offices in Abbott Park, Illinois. At all times material to this civil action, Abbott has transacted business throughout the United States, selling and distributing its drugs, including but not limited to those identified in this Complaint, to purchasers within this District.

V. THE LAW

A. The False Claims Act

13. The FCA provides in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

14. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

B. The Federal Anti-Kickback Statute

15. Congress first enacted the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), in 1972 to protect the integrity of Medicare and Medicaid. Congress strengthened the statute in 1977, and again in 1987, to ensure that kickbacks masquerading as legitimate transactions would not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

16. The anti-kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical items, including items provided under Medicare and Medicaid. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> > (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –
> >
> > > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > >
> > > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment

> > > > may be made in whole or in part under a Federal health care program,
> > > >
> > > > shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
> > > >
> > > > (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --
> > > >
> > > > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > > >
> > > > (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
> > >
> > > shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

VI. THE FEDERAL HEALTHCARE PROGRAMS

17. Medicaid and Medicare were created to provide access to healthcare for elderly, indigent or disabled residents of the United States.

A. The Medicaid Program

18. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

19. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

20. The federal portion of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50%, and as high as 83%.

21. The Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

22. The Medicaid programs of all states reimburse for prescription drugs.

23. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

24. By becoming a participating supplier in Medicaid, suppliers agree to abide by all laws, regulations, and procedures applicable to that program, including those governing reimbursement.

B. The Medicare Program

25. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain healthcare services and items. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. 42 U.S.C. §§ 426-426a, 1395o.

26. HHS is responsible for the administration and supervision of the Medicare program. CMS is an agency of HHS and directly administers the Medicare program. The Medicare program has several parts, including Medicare Part B ("Supplementary Medical Insurance for the Aged and Disabled"), which covers physician services, as well as durable medical equipment ("DME") and certain drug products and supplies. 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

27. Medicare Part B generally covers drugs which are provided either: (a) incident to a physician's service and cannot usually be self-administered (42 C.F.R. § 410.26 (*e.g.*, certain oncology drugs)); or (b) in conjunction with the medical necessity of an infusion pump or nebulizer or other DME device payable under Medicare's DME benefit. 42 C.F.R. §§ 405.517, 414.701.

28. During the relevant time period, CMS contracted with private insurance carriers ("Contractors") to administer and pay Part B claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the Contractors act on behalf of CMS. 42 C.F.R. § 421.5(b).

29. Contractors receive, process and pay claims under Medicare Part B for drugs from various Medicare providers and suppliers. Typically, once a contractor approves a claim, the contractor then submits a payment request to a Medicare bank account funded by federal funds.

C. Drug Reimbursement Under Medicaid and Medicare

30. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-97, requires pharmaceutical companies to submit to the Food and Drug Administration ("FDA") a listing of every drug product in commercial distribution. 21 U.S.C. § 355. The FDA provides for the assignment to each listed drug product of a unique 11-digit, 3-segment number, known as the National Drug Code ("NDC"). FDA has assigned approximately 170,000 NDCs to drug products. The drugs and corresponding NDCs at issue in this case are listed below:

DRUG	NDC#
Sodium Chloride Injection	00074196607
Water for Injection 30 ml	00074397703
Vancomycin HCl 500 mg	00074433201
Water for Injection 10 ml	00074488710
Water for Injection 20 ml	00074488720
Sterile Water for Injection	00074488750
Sodium Chloride Injection	00074488810
Sodium Chloride Injection	00074488820
Sodium Chloride Irrigation	00074613802
Sodium Chloride Irrigation	00074613803
Sodium Chloride Irrigation	00074613822
Sterile Water for Irrigation	00074613902
Sterile Water for Irrigation	00074613903

Sterile Water for Irrigation	00074613922
Vancomycin HCl 5 gm	00074650901
Vancomycin HCl 1 gm	00074653301
Vancomycin HCL 500 mg Add-Vantage	00074653401
Vancomycin HCl 1 gm Add-Vantage	00074653501
5% Dextrose in Water 50 ml	00074710013
5% Dextrose in Water 100 ml	00074710023
Sodium Chloride Injection	00074710102
Sodium Chloride 0.9% 50ml	00074710113
Sodium Chloride 0.9% 100 ml	00074710123
Dextrose Injection	00074712007
Sodium Chloride Irrigation	00074713809
Sterile Water for Irrigation	00074713909
Dextrose 5%/ Kcl/NaCl 1000 ml	00074790209
Dextrose Injection	00074792202
5% Dextrose in Water 500 ml	00074792203
5% Dextrose in Water1000 ml	00074792209
Dextrose Injection	00074792336
Dextrose Injection	00074792337
Dextrose 5% and 0.225% NaCL Injection	00074792409
Dextrose 5% and 0.225% NaCL Injection	00074792609
5% Dextrose/ NaCl 0.9% 1000 ml	00074794109
Sodium Chloride Irrigation	00074797205
Sterile Water for Irrigation	00074797305
Sodium Chloride 0.9% 250 ml	00074798302
Sodium Chloride 0.9% 500 ml	00074798303
Sodium Chloride 0.9% 1000 ml	00074798309
Sodium Chloride Injection	00074798436
Sodium Chloride Injection	00074798437
Sodium Chloride Injection	00074798509
Water for Injection1000 ml	00074799009
Acyclovir Sodium 500 mg	00074442701
Acyclovir Sodium 1 gm	00074445201

31. Drug manufacturers, such as Abbott, have not typically submitted claims for reimbursement to federal health care programs. Instead, Abbott marketed its products to its Customers, who then purchased the products either directly or through wholesalers based on a price the Customers negotiated with Abbott. In addition to using wholesalers, Customers also

purchased Abbott products through group purchasing organizations ("GPO"), who negotiated prices on behalf of Abbott's Customers. However, as described in ¶¶ 111-138 below, Abbott also had a business unit that, among other activities, operated home infusion pharmacies and actually submitted reimbursement claims for drugs on behalf of various clients.

32. Abbott's Customers then submitted claims for payment for Abbott products to Medicare and Medicaid after dispensing or administering Abbott drugs. Medicare and Medicaid reimbursed some of the claims submitted by Abbott's home infusion pharmacies. In other instances, Abbott administered reimbursement claims for certain home infusion clients and collected portions of those clients' Medicare and Medicaid reimbursements as compensation for those services.

33. For the most part, in the Medicaid program, claims submitted by retail pharmacies are processed and tracked using the NDC of the drug.

34. The Medicare program generally uses the Healthcare Common Procedural Coding System ("HCPCS") to reimburse for drugs. The HCPCS utilize 5-digit alphanumeric codes to identify and bill for medical products and supplies. The codes at issue here are listed below:

HCPCS	**Description**
J2912	Sodium Chloride, .9 percent, per 2 ml
J3370	Vancomycin HCl, 500 mg
J7030	Normal Saline Solution, 1000 cc
J7040	Normal Saline Solution, 500 ml
J7042	5 percent Dextrose/Normal Saline Solution, 500 ml
J7050	Normal Saline Solution, 250 cc
J7051	Sterile Saline or Water, up to 250 cc
J7060	5 percent Dextrose/Water, 500 ml
J7070	D-5-W, 1000 cc
J7110	Dextran 75, 1000 ml
J7130	Hypertonic Saline Solution, 50 or 100 mEq, 20 cc vial

35. During the relevant period, Abbott usually reported prices to various price publishers and services on an annual basis. The price publishers used the information to publish pricing compendia.

36. The reimbursement amounts for claims submitted by Abbott or Abbott's Customers for the drugs at issue in this Complaint were directly influenced by Abbott's false price representations. The information contained in the published pricing compendia was used by most third party payor insurance companies, including the Medicare and Medicaid programs, in determining the reimbursement rates for prescription drugs. Abbott documents show that Abbott knew of the impact of its price representations on government reimbursement on claims submitted by its Customers for its drugs. Abbott documents also show that the company actively marketed the government-funded profits or "spreads" on its drugs created by its false price representations.

37. No governmental payor knew of or sanctioned Abbott's conduct as set forth in this Complaint, i.e., its deliberate manipulation of its published prices for certain of its products to induce its Customers to purchase those products.

D. Medicaid Reimbursement Formulas

38. When reimbursing for drugs, the State Medicaid programs' goal has been to pay an amount which, in the aggregate, reflects the lower of (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee, or (2) a provider's usual and customary charges to the general public. To determine the EAC for a covered drug, State

Medicaid programs are required to develop reimbursement formulas that must be approved by the Secretary of HHS. 42 C.F.R. §§ 447.331, 447.332, and 447.333 (2005).

39. While the specific reimbursement formulas vary from state to state, the various State Medicaid programs have generally reimbursed for each drug based on the lowest of (a) the EAC as set by the states, (b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Reimbursement Boards, or (c) the providers' usual and customary charge. For multiple source drugs subject to a federal upper limit, states must in the aggregate not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332 and 447.333 (2005).

40. The states' methodology for arriving at EAC includes:

A. discounting a percentage off of the Average Wholesale Price ("AWP");

B. adding a percentage to the Wholesale Acquisition Cost ("WAC") ; and/or,

C. requiring the drug companies to certify prices directly in writing to the Medicaid program in response to state requests for particular pricing information.

41. AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail Customer who then administers it to a patient. WAC is used to refer to the price at which a pharmaceutical firm typically sells a drug to wholesalers who would then resell it to a retail Customer.

42. While the majority of states use published AWPs to calculate reimbursement, approximately six states (Alabama, Florida, Maryland, Massachusetts, Rhode Island and Texas) have used the wholesale acquisition cost ("WAC") to set the EAC.

43. The AWPs and WACs relied upon by the State Medicaid programs have generally been those published by (1) Thomson Publishing, publisher of the *Red Book* and various other price publications, (2) First Databank, publisher of the *Blue Book* and other electronic price publications; or (3) Medi-Span, Inc., publisher of an electronic or automated price service and the Hospital Formulary Pricing Guide. Thompson Publishing, First Databank and Medi-Span, Inc. are hereafter referred to as the "Publishers" and their various publications and data services are hereinafter referred to as "Price Publications."

44. In addition to relying on the manufacturers' reported prices as published in the Price Publications, some State Medicaid programs also received price representations directly from manufacturers, and relied on these representations to confirm the accuracy of the figures they use to determine state reimbursement amounts. For example, the State of Texas required drug companies to submit their prices directly to the Texas Medicaid program in a signed certification attesting to the accuracy of the price information.

E. Medicare Reimbursement Formulas

45. From 1992 through 1997, Medicare based its reimbursement for multi-source generic drugs, the drugs at issue here, at the lower of the EAC or the median AWP of all generic forms of a drug. 42 C.F.R. § 405.517 (1992-1998). In general, Medicare relied on median AWPs to set reimbursement rates.

46. From January 1, 1998, until December 31, 1998, Medicare based its reimbursement for all generic forms of a drug at 95% of the median AWP for the drug. Balanced Budget Act of 1997, 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1998).

47. From 1999 through 2004, Medicare based its reimbursement for all generic forms of a drug at the lower of (1) 95% of the median published AWP for the drug; or (2) the AWP of the least expensive brand-name drug. 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1999-2004).

48. After the reimbursement amount is calculated, Medicare pays 80 percent and the Medicare beneficiary is responsible for the remaining 20 percent co-payment. If the Medicare beneficiary is also a Medicaid recipient, the Medicaid program generally pays the 20 percent Medicare co-payment.

49. Medicare generally relied upon the AWPs published by Thomson Publishing in its annual national compendium known as the *Drug Topics Red Book* ("*Red Book*"), as well as *Red Book* monthly updates to set reimbursement rates for covered drugs.

VII. ABBOTT'S SCHEME

50. From at least on or before January 1, 1991, and continuing through 2001, Abbott defrauded the United States by knowingly causing the Medicare and Medicaid programs to pay false or fraudulent claims for dextrose solutions, sodium chloride solutions, sterile water, Vancomycin and Acyclovir Sodium.

51. The specific dextrose solutions, sodium chloride solutions, sterile water, Vancomycin and Acyclovir Sodium products at issue herein are identified by NDC or HCPCS Code in ¶¶ 30 and 34 above and are hereinafter referred to jointly as the "Drugs."

52. Dextrose solutions, sodium chloride solutions, and sterile water are generic, water-based solutions used to facilitate the intravenous infusion of other drugs and for fluid replacement, and are commonly referred to as large volume parenterals ("LVPs").

53. Vancomycin is a powerful, intravenous antibiotic that Abbott has sold as a generic drug since 1988.

54. Acyclovir Sodium ("Acyclovir") is an antiviral drug used to treat several opportunistic viral infections, some of which are associated with HIV/AIDS.

55. Abbott marketed and sold its products, including the Drugs, to Customers.

56. The Customers purchased the products either directly from Abbott, through a GPO contract or through wholesalers.

57. The amount paid by a Customer was typically based on a price negotiated with Abbott or the GPO.

58. Regardless of the method of purchase, Abbott's Customers submitted claims for payment to Medicare and Medicaid when an Abbott product was administered to a program beneficiary. The claims submitted by Abbott's Customers were paid at amounts directly influenced by Abbott's false and fraudulent prices.

59. Abbott routinely disseminated false pricing information for the Drugs to the Pricing Publications. Abbott employees typically reported the false and fraudulent prices to the Price Publications annually, although they sometimes did so more often. On most occasions, Abbott reported inflated "List Prices" or "Direct Prices" (both referred to hereinafter as LP), WACs and/or AWPs. A LP is supposed to reflect the price paid by a Customer that buys drugs directly from Abbott and not through a wholesaler.

60. When Abbott reported a LP, some Price Publications (*e.g.*, *Blue Book*, which provided pricing information for the vast majority of the state Medicaid programs) calculated

Abbott's AWPs by applying a markup – usually 18.75% – to the LPs. Abbott was aware of how the Price Publications set its AWPs and knew (1) that the markup remained constant and (2) that its LPs ultimately controlled the AWP reported by the Price Publications for many of its products. Abbott reported WACs for several of its drugs as well, but during the time period covered by the Complaint, the Price Publications used Abbott's LPs (plus the standard markup) to set the AWPs used by the Medicaid and Medicare programs.

61. In some circumstances, Abbott itself calculated and supplied the AWP which it sought to have published.

62. For example, in a January 16, 1996 letter from Abbott's Reimbursement Manager to Medi-Span, Abbott directly reported AWPs for two of its products.

63. Abbott documents also confirm its knowledge that the LPs it reported directly impacted the AWP. In a March 20, 1995 e-mail between Abbott employees regarding the reporting of new Vancomycin LPs, one employee notes, "Please notify Red Book and Medi-Span of these changes ASAP. They are the sources for creating the AWP that is important to [Abbott's] Alternate Site [sales division]."

64. Abbott also submitted false and fraudulent prices directly to state Medicaid programs. In an October 1, 1997, Abbott "Medicaid Coordinator" Tena Brown represented in a letter to the State of Texas Medicaid Program that the price on Abbott's Vancomycin 1 GM Fliptop vial- sterile, NDC 00074-6533-01 ("Vancomycin 1 GM FTV") was $583.70 for a package of 10, or $58.37 a unit. That led the Texas Medicaid program to set reimbursement for

Vancomycin 1 GM FTV at that price ($58.37 a unit). At the time, Abbott sold Vancomycin 1 GM FTV to certain Customers for $5.53 per unit, through a GPO called Oncology Solutions.

65. With extremely few exceptions, Abbott reported increasingly higher prices for the Drugs from at least on or before January 1, 1991 through 2001. At the same time, the prices Abbott actually charged to its Customers decreased or remained the same.

66. Abbott knew that the prices which it reported to the Price Publications directly affected reimbursement amounts paid by the Medicaid and Medicare programs. As Abbott's Manager for Reimbursement noted in an April 26, 1995 memorandum, "[h]aving a published [LP] that is high allows a provider to bill at that list price." The false or fraudulent prices Abbott reported to the Price Publications inflated government reimbursement amounts on claims submitted by Abbott's Customers for the Drugs. A chart setting out some examples showing the difference between the prices at which Abbott actually sold its drugs and the false prices reported by Abbott is attached hereto as **Exhibit 1**.

67. Abbott manipulated its LPs, AWPs and WACs to induce its Customers to purchase Abbott's products, including the Drugs, by marketing the huge profits that would result to its Customers.

68. Abbott was well aware of how the Government used its pricing information to reimburse Abbott products. For example, Abbott organized an internal entity known as the "Medicare Working Group." The group (1) was organized by high level Abbott executives, (2) involved representatives responsible for reimbursement issues from all major Abbott divisions, and (3) discussed and organized efforts to influence government reimbursement for drugs.

69. Documents from the Medicare Working Group establish that Abbott knew that AWP is based upon Abbott's reported price plus, according to the Medicare Working Group documents, "a mark-up of 15-20%." Minutes from a January 21, 1997 meeting note that this AWP based on Abbott's reported prices is subsequently reported in "the Red Book, Blue Book and Medispan Book and is used by Medicare, Medicaid and Commercial insurance carriers to determine reimbursement levels."

70. Neither the Medicaid nor the Medicare programs knew of or sanctioned Abbott's conduct as set forth in this Complaint, *i.e.*, the deliberate manipulation of its published prices to induce its Customers to purchase the Drugs. Abbott never disclosed the price reporting practices for the Drugs identified in this Complaint to the Medicaid or Medicare programs.

A. Vancomycin

71. Abbott first introduced its generic Vancomycin in 1988. Abbott's scheme to defraud the United States by causing inflated Vancomycin reimbursements ran from approximately 1989 through 2001. Over that time period, Medicare and Medicaid paid in excess of $75 million for Abbott's Vancomycin.

72. During that time period, Abbott reported increasingly higher LPs and AWPs for Vancomycin to the Price Publications while the actual contract prices at which Abbott sold Vancomycin to its Customers decreased significantly.

73. Abbott sold its Vancomycin in several doses and forms. The Vancomycin 1 GM FTV was the most common dose of Vancomycin reimbursed by Medicare and Medicaid.

Abbott's false and fraudulent price reporting on its Vancomycin 1 GM FTV represents how Abbott reported false and fraudulent prices on its other Vancomycin products.

74. When Abbott first introduced its Vancomycin 1 GM FTV in 1988, the published per unit AWP was $25.20. By early 2001, Abbott reported false prices that drove the AWP for Vancomycin 1 GM FTV to $76.42. At the same time, the price at which Abbott's Vancomycin was widely available to purchasers decreased to under $4.00 by early 2001; the difference (and potential profit) between the reported price and the actual selling price for Vancomycin 1 GM FTV was as great as $72.42 a dose, or more than 18 times the actual price at which Abbott sold Vancomycin 1GM FTV.

75. Abbott fully controlled and manipulated the AWPs for Vancomycin 1 GM FTV to boost its Vancomycin sales at the expense of third party payors, including Medicare and Medicaid.

76. Abbott's manipulation of its reported Vancomycin prices between 1989 and 2001 created spreads sufficient to induce increased sales of that drug. Internal memoranda from senior Abbott sales staff reveal that Abbott actively knew about and marketed the large spreads on several of its drugs, including Vancomycin. Those efforts proved successful; the percentage of Abbott's Vancomycin sales reimbursed by Medicaid increased from less than 10% in 1991 to approximately 70% in 2000.

77. Abbott's reporting of Vancomycin prices in 1995 exemplifies the manner in which Abbott manipulated the price of Vancomycin to maintain and grow its market share. In March 1995, Abbott temporarily reported dramatically lower LPs and AWPs for Vancomycin.

Prior to the March 1995 LP/AWP price change, the Price Publications listed a per unit LP of $50.90 for Abbott's Vancomycin 1 GM FTV, and a per unit AWP of $60.44 for that drug.

78. In late March 1995, Abbott reported a new LP of $15.00 for a unit of Vancomycin 1 GM FTV. Based on this new information from Abbott, the Price Publications published revised per unit prices for Vancomycin 1 GM FTV. They reported a LP of $15.00 and an AWP of $17.81.

79. Abbott received numerous complaints from Customers over the resulting decrease in the spread. Abbott deliberated internally on whether and by how much Abbott should again increase its spread so that it could reestablish the inducement that had come to be expected by its Customers. Abbott documents show Abbott's pricing personnel carefully considering the additional profits they could generate for Abbott's Customers if they artificially re-inflated the reported prices for Vancomycin 1 GM FTV at various levels.

80. Abbott subsequently reversed its earlier decision to lower its reported prices and instead raised its reported Vancomycin prices. In early May 1995, Abbott reported a new per unit LP for its Vancomycin 1 GM FTV of $32.95. The revised AWP for Abbott's Vancomycin 1 GM FTV became $39.13 (once the Price Publication applied the standard markup).

81. That reported price increase proved insufficient. Later that same month (May 1995), Abbott reported yet another set of prices for Vancomycin. The LP Abbott reported for its Vancomycin 1 GM FTV rose to $52.94 and its AWP rose to $62.86 (once the Price Publication applied the standard markup).

82. Thereafter, Abbott reported higher Vancomycin LPs and AWPs to the Publishers each year, despite decreases in its actual prices to Customers for Vancomycin over that same period. The AWP for Abbott's Vancomycin 1 GM FTV peaked at $76.42 per unit in early 2001 at the same time that the actual sales price was less than $4 per unit.

83. The false prices reported by Abbott directly impacted the amount Medicaid and Medicare reimbursed for Vancomycin. For example, in 1999 Abbott's Vancomycin 1 GM FTV was widely available for approximately $4.75 a unit. Yet, Abbott reported a per-unit Vancomycin LP in 1999 – which served as the baseline for determining the AWP – to First DataBank of $64.35. As a result, the 1999 AWP for Vancomycin 1 GM FTV was set at $76.42.

84. New York State's Medicaid program relied on the First DataBank prices to set its reimbursement rate for the Vancomycin 1 GM FTV. New York State's Medicaid reimbursement rate for the Vancomycin 1 GM FTV in 1999 was $68.77; the AWP for Vancomycin 1 GM FTV was $76.42 at the time. New York's reimbursement for Vancomycin 1 GM FTV was AWP minus 10%, a reimbursement formula generally similar to those of other states. Abbott's false price representations created a profit spread of approximately $64.02 for Abbott's Customers, on a drug that Abbott sold to those same Customers for approximately $4.75 a unit. The spread between the New York state Medicaid reimbursement for Vancomycin 1 GM FTV – directly influenced by Abbott's false price reporting – and the actual acquisition cost was 1,348%. The profit to Abbott's Customers was 13.5 times the typical acquisition cost for the drug.

85. Abbott's practice of price manipulation continued into early 2001. At that time, Abbott reported new, lower WACs to the Price Publications for many of its drugs, including

Vancomycin, without also reporting new LPs or AWPs. At the time Abbott submitted the new prices in early 2001, it had been under investigation by the Government for pricing fraud. In addition, members of the House Ways and Means Committee accused Abbott of engaging in price reporting misconduct that threatened public safety in the fall of 2000; the Centers for Disease Control had expressed concerns that over-prescription of Vancomycin could lead to the growth in the population of Vancomycin-resistant bacteria. Also, in October 2001, an Abbott joint venture, TAP Pharmaceuticals, Inc. paid $875 million to the Government to resolve its criminal responsibility and civil liability for fraudulent pricing and kickbacks in connection with the marketing of a drug called Lupron. When Abbott submitted reduced WACs, First DataBank changed the way it calculated Abbott's AWP. First Databank personnel set new AWPs for Abbott products by applying a 25% markup to the newly supplied WACs instead of setting Abbott's AWPs by applying a 18.75% markup to Abbott's still inflated LPs. Abbott tried to convince First DataBank personnel not to set Abbott's AWP by reference to these new, lower WACs; Abbott wanted First DataBank to continue to use Abbott's then still inflated LPs to maintain its inflated AWPs. First DataBank refused Abbott's request. Ultimately, Abbott reduced its LPs and WACs to reflect the average sales price for the Drugs on April 30, 2001.

86. The switch to using the lowered WACs drastically dropped Abbott's reported AWPs in 2001. For Abbott's Vancomycin 1 GM FTV, the AWP dropped from $76.42 per unit in early 2001 (when AWP was determined using the inflated LPs) to $17.72 per unit in 2001 (when AWP was set using the revised, lowered WACs). By 2002, the AWP for this product was down to $6.06 a unit.

87. As a result of the drop in AWP, the spread on the reimbursement by Medicare and Medicaid was reduced from $60-$70 a unit to approximately $2.00 a unit.

88. Abbott's Customers recognized that Abbott was responsible for creating and maintaining the spread. Numerous Customers complained to Abbott or the group purchasing organizations (GPOs) who negotiated prices on behalf of Abbott's Customers. A large Customer of Abbott went so far as to demand restitution for the almost $10.5 million in lost profits due to the decrease in spread resulting from Abbott's 2001 submission of lowered prices to the reporting agencies.

89. Internal memoranda from senior Abbott sales staff reveal that Abbott actively knew about and marketed the large spreads on several of its drugs, including Vancomycin, as an inducement to purchase Abbott's drugs.

90. Abbott's share of the Medicaid market has dropped steadily since the more accurate prices started being published in 2001 and thereafter went from approximately 70% in early 2001 to approximately 20% in 2004.

B. Large Volume Parenterals

91. In addition to false price reporting for Vancomycin, Abbott engaged in similar conduct with respect to its LVPs.

92. LVPs are essentially sterile water, usually mixed with either salt (sodium chloride) or sugar (dextrose). LVPs are cheap to produce and are sold at very low prices.

93. One of the most commonly utilized Abbott LVPs was 5% Dextrose in Water, 500 ml, NDC # 00074-7922-03 ("5% Dextrose 500 ml").

94. In 1993, Abbott's 5% Dextrose 500 ml could be widely purchased for as little as $1.80 for a 500ml bag.

95. The Red Book AWP for 5% Dextrose 500 ml in 1993 was $8.72.

96. Two years later, in 1995, the price for Abbott's 5% Dextrose 500ml was widely available for even less; one wholesaler was selling it at $1.50 for a 500 ml bag.

97. During the same two year period from 1993 to 1995 that the actual prices dropped, Abbott twice reported higher prices to the Price Publications for 5% Dextrose 500 ml. The AWP – based on Abbott's representations – increased by 5% in 1994 to $9.16 and was increased by an additional 3% in 1995 to $9.43.

98. Thus, while Abbott's price to the wholesaler dropped by 20% between 1993 and 1995 (from $1.80 to $1.50), Abbott caused its AWP to increase by 8%. By 1995, the spread between the AWP and the resale price of that wholesaler was 628%.

99. Abbott sold these products directly to Customers at prices comparable to those offered by the wholesaler.

100. Abbott continued to report increasing prices for 5% Dextrose 500 ml after 1995. By reporting increasingly inflated LPs, Abbott caused the Red Book AWP for 5% Dextrose in Water, 500 ml, NDC # 00074-7922-03 to increase in 1996 to $9.71, in 1997 to $10.20, in 1998 to $10.71, in 1999 to $11.25 and in 2000 to $11.80. Medicaid and Medicare used these reported prices to set their reimbursement levels. At the same time, Abbott regularly sold the product to its Customers for $1.50 or less per bag of the water-based solution.

101. Abbott's reporting of increasingly false and fraudulent prices for its 5% Dextrose 500ml reflects the manner in which Abbott implemented its scheme for all of the LVPs during the relevant time period. Abbott engaged in identical conduct with respect to the "prices" and marketing of the other LVP products and package sizes identified by NDC and HCPCS code in ¶¶ 30, 34 of this Complaint.

102. Abbott used the false and fraudulent prices Abbott reported to the Price Publications for these water solutions to manipulate reimbursement; the reported prices did not reflect the actual prices Abbott was charging to its Customers.

103. Due to Abbott's conduct, Abbott's Customers submitted inflated claims to Medicare and Medicaid and received millions of dollars in inflated reimbursement for these water and water-based solutions. Abbott profited off the scheme by increasing its sales volume and profits. Medicare and Medicaid have paid Abbott's Customers in excess of $100 million for Abbott's LVPs when the typical acquisition costs for those Customers were a fraction of that amount.

C. Acyclovir Sodium

104. Acyclovir Sodium (Acyclovir) is an antiviral drug used to treat several infections. The brand version, called Zovirax, was originally manufactured by Glaxo Welcome, Inc. Abbott began selling its generic version of the drug on April 22, 1997.

105. At the time Abbott launched its versions of Acyclovir in 1997, it reported a LP of $80.00 for the 500MG Dose of its generic version of Acyclovir (NDC#00074-4427-01). The

1997 Blue Book AWP for Abbott's Acyclovir Sodium 500MG was $95.00 (reflecting the standard price publication mark up on Abbott products of 18.75%).

106. By 1999, Abbott had raised its reported LP for its Acyclovir Sodium 500MG to $88.20; the AWP for that dose of Abbott's Acyclovir Sodium had risen to $104.74.

107. Yet, competition among manufacturers of Acyclovir drove the contract prices for the drug down sharply. In 1997, Abbott's Acyclovir Sodium 500MG could be purchased for $30.00. By 2000, the typical purchase price for Abbott's Acyclovir Sodium 500MG had eroded to around $11.

108. Thus, the spread on Abbott's Acyclovir went from as much as 316% at product launch in 1997 to as much as 960% by 2000.

109. Abbott actively marketed the reimbursement spread on Acyclovir to Customers, including Ven-A-Care, the relator in this matter. Ven-A-Care operated a home infusion pharmacy that largely serviced HIV/AIDS patients. On or around May 30, 1997, an Abbott national account manager directly marketed the spread on its Acyclovir Sodium to Ven-A-Care. That national account manager sent documents reflecting the spread on Abbott's Acyclovir and had conversations with Ven-A-Care where he explicitly marketed the spreads on Abbott's Acyclovir products.

110. On April 30, 2001, Abbott reported new LPs and WACs for its Acyclovir products. As noted above, the price reporting compendia changed the method it used to calculate Abbott's AWP. First Databank began using Abbott's WAC and applying a 25% markup. The LP for Abbott's Acyclovir Sodium 500MG dropped from $88.20 to $4.00; the WAC dropped to

$3.81. The per unit AWP – based on a 25% markup from the $3.81 WAC – for Abbott's Acyclovir Sodium 500MG dropped from $104.74 to $4.76. The revised LP, WAC and AWP was in keeping with the actual contract price for Abbott's Acyclovir Sodium 500MG, which by mid-2001 was around $4.00 a unit.

D. Abbott's Home Infusion Pharmacies, Home Infusion Partnerships and Consignment Arrangements.

1. Home Infusion Pharmacies

111. From approximately 1982 until, upon information and belief, 2003, Abbott owned and operated its own Home Infusion Pharmacies ("Abbott HI Pharmacies") as part of its Hospital Products Division's ("HPD"), Alternate Site Home Infusion Department.

112. Abbott's HI Pharmacies were located at various times in Atlanta, Georgia, Chicago, Illinois, Los Angeles, California, and in New Jersey. At some point in that period, the Abbott HI Pharmacy in Atlanta Georgia closed.

113. Abbott billed Medicare and Medicaid for products and services dispensed by the Abbott HI Pharmacies using Abbott's EIN number and Abbott's own Medicare and Medicaid provider codes.

114. Abbott HI Pharmacies stocked and dispensed Abbott products, including, without limitation, products identified in this Amended Complaint in ¶ 30, as well as other products produced and sold by Abbott and other manufacturers. Upon information and belief, Abbott stocked its own products at or near the manufacturing costs for those products. Upon information and belief, Abbott was able to acquire other manufacturers' drugs at reduced, contracted prices.

115. The Abbott HI Pharmacies billed Medicare and Medicaid through the "Abbott Reimbursement Department" in Abbott's HPD Alternate Site Home Infusion Department.

116. Each of the Abbott HI Pharmacies would operate as follows:

A. The Abbott HI Pharmacies would receive patient prescriptions from physicians, hospitals, outpatient clinics or other care providers.

B. Abbott's Reimbursement Department would ascertain whether the referred patient was eligible for reimbursement for his or her prescription costs through Medicare, Medicaid or a third party insurer.

C. Upon receipt of the prescriptions, the Abbott HI Pharmacies would fill the prescription and would, upon information and belief, at times provide pharmacist services.

D. After the prescriptions were filled by an Abbott HI Pharmacy, the Abbott Reimbursement Department would bill either Medicare, Medicaid or a third-party insurer for the dispensed drug or product, depending upon patient eligibility.

E. For those patients covered under Medicare or Medicaid, a reimbursement clerk in the Abbott Reimbursement Department would complete a paper or, at a later point, an electronic, Medicare HCFA 1500 form seeking reimbursement from Medicare or a Medicaid reimbursement form.

117. The HCFA 1500 forms or Medicaid reimbursement forms submitted by the Abbott Reimbursement Department would reflect Abbott's EIN number and provider number as the entity to be reimbursed.

118. Depending upon the drug and the state program, Medicaid would typically pay to Abbott the AWP or WAC-based reimbursement for drug or product for which Abbott's HI Pharmacy billed. Medicare would typically pay to Abbott the AWP-based reimbursement for drug or product for which Abbott's HI Pharmacy billed. Abbott would retain for itself as a profit the difference between the cost of the drug or product to Abbott and the amount of the AWP-based reimbursement ("Abbott HI Pharmacy spread").

119. Upon information and belief, Abbott did not disclose the Abbott HI Pharmacy spreads to the Medicare or Medicaid programs when it submitted reimbursement forms.

120. The amounts Abbott HI Pharmacies were reimbursed by Medicare and Medicaid regularly exceeded the cost to Abbott in stocking and dispensing the drugs and products dispensed by the Abbott HI Pharmacies – including its own.

121. In the case of the Abbott Drugs identified in this Complaint, Abbott's HI Pharmacies were reimbursed inflated amounts for any claims they submitted for those Drugs due to Abbott's fraudulent price reporting scheme.

2. Abbott's Home Infusion Partnerships and Consignment Arrangements

122. From approximately 1984 until, upon information and belief, 2003, Abbott HPD's Alternate Site Home Infusion Department entered into home infusion partnerships ("HI Partnerships") with various hospitals, care facilities and other medical entities. These HI Partnerships permitted Abbott's home infusion partners ("HI Partners") or – in some instances Abbott – to bill government health programs on behalf of its HI Partners for the Drugs identified in ¶ 30 at inflated reimbursement levels.

123. Abbott had at least 20 to 25 home infusion partners ("HI Partners") in these partnerships including, but not limited to:[3] University of Michigan's HomeMed, Children's Memorial Hospital of Chicago, Care Partners, Baylor, Harris Methodist, UniHealth, Intermountain, Cedars Sinai, University of Virginia, Seattle Children's Hospital, Cleveland Clinic, and University Hospitals of Cleveland.

124. Abbott entered into standard partnership agreements with the HI Partners and others. Under the terms of the partnership agreements, Abbott would:

A. Provide its HI Partners Abbott drugs and products free of charge on a consignment basis, including but not limited to, the Drugs identified in ¶ 30 of this Complaint;

B. Provide its HI Partners agreed upon services, including, on occasion, "reimbursement services;" and

C. Add the HI Partner to a group purchasing organization of which Abbott was a member, so that the HI Partner, or Abbott on behalf of the HI Partner, could purchase drugs and products that Abbott did not manufacture or sell ("Other Non-Abbott products") at a substantially reduced contract rate.

125. The HI Partner would dispense the drugs or products from its pharmacy. If the drug or product was an Abbott product, that product would be a consigned product that the HI

[3] These HI partners are described herein as identified by an Abbott witness. For some of these HI partners, the witness did not provide full and complete name information.

Partner would not pay for on an individual basis, or at any time prior to when the HI Partner billed Medicare or Medicaid.

126. As part of its "reimbursement" services for some HI Partners, Abbott's Reimbursement Department would submit claims to Medicare, Medicaid and other third party payors for drugs, medical devices and medical services on the HI Partner's behalf, using the HI Partner's EIN number and Medicare and Medicaid provider codes.

127. For patients covered under Medicare or Medicaid, an Abbott reimbursement clerk in the Reimbursement Department would complete a paper or, at a later point, electronic, Medicare HCFA 1500 form seeking reimbursement from Medicare, or the appropriate Medicaid reimbursement form seeking reimbursement from a State Medicaid program on behalf of the HI Partner.

128. Abbott provided reimbursement services to, among others, Care Partners, University of Michigan, Children's Hospital and the University of Virginia.

129. If Abbott was providing reimbursement services to an HI Partner, Abbott's Reimbursement Department would collect reimbursements from Medicare, Medicaid and other third party payors for claims submitted on behalf of that HI Partner. Those reimbursement amounts were collected in lock box bank accounts that, upon information and belief, were maintained in the name of the HI Partner or Abbott.

130. Upon information and belief, Abbott would never bill the HI Partners for the drugs and products it consigned to them, and would never expect payment for them. Abbott's payment for the consigned Abbott drugs would be some percentage of the HI Partner's entire pool

of collections from Medicare, Medicaid and third party payors, regardless of whether it was Abbott or the HI Partner that submitted the claim.

131. Under the Consignment Partnership Agreements, the HI Partners would never pay Abbott individual amounts for the drugs or products consigned to the HI Partner. The Medicare and Medicaid drug reimbursements were used by Abbott to compensate it for billing and consulting services not related to the provision of patient care.

132. For example, a December 1996 Consignment Partnership Agreement, required a HI Partner to pay Abbott 45.1 % of its gross revenue collections for all of its IVIG treatment, including any administration fee and/or any drug ingredient cost. Thus, Abbott would receive a percentage of any inflated reimbursement spreads for the Drugs identified in ¶ 30 of this Complaint that were provided to its HI Partners on consignment.

133. Abbott never disclosed to the Medicare or Medicaid programs that it was directly profiting from the reimbursement spreads in the above-described arrangement with the HI Partners.

134. If an HI Partner would not contract for reimbursement services, the HI Partner would submit the claims to Medicare and Medicaid and directly collect the reimbursements. However, Abbott would still consign its drugs and products to the HI Partner and still share in a percentage of the total collections collected by the HI Partner.

135. Several state Medicaid programs would reimburse for Abbott drugs covered by this arrangement at amounts tied to the AWPs or WACs for those drugs. Medicare also reimbursed for Abbott drugs covered by these arrangements at amounts tied to the AWPs for the

Abbott drugs. That amount would then be paid to the HI Partner, who in turn would provide a percentage share to Abbott of its entire collections as payment for various types of categories of services.

136. The cost to Abbott in stocking the HI Partner's warehouses with Abbott and non-Abbott drugs and products was far less than the amounts reimbursed by Medicare and Medicaid for those drugs and products.

137. Abbott did not disclose to the Medicare and Medicaid programs that the drugs and products it sought reimbursement for from Medicare or Medicaid actually cost Abbott far less to consign to the HI Partner than the ultimate Medicare or Medicaid reimbursement amount.

138. In the case of the Abbott Drugs identified in this Complaint, Abbott's percentage of HI Partner reimbursements Abbott that collected was improperly inflated due to Abbott's fraudulent price reporting scheme.

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

139. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

140. Abbott knowingly caused or caused to be presented false or fraudulent claims for payment or approval to the United States for the Drugs for reimbursement that were substantially higher than providers' actual acquisition costs for the Drugs and based on reported prices that were fraudulently and artificially manipulated by Abbott. Abbott knowingly used the spread as an unlawful inducement in violation of the federal anti-kickback statute, causing resulting false and fraudulent claims to be submitted.

141. By virtue of the false or fraudulent claims that Abbott caused to be made, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False Records or Statements to Cause Claims to be Paid)
(31 U.S.C. § 3729(a)(2))

142. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

143. Abbott knowingly made, used, or caused to be made or used, false records or statements – *i.e.*, the false certifications and representations made or caused to be made by defendants to state Medicaid programs when seeking to ensure that the Medicaid programs would reimburse for the Drugs, and the false representations to the Publishers upon which Medicare and Medicaid relied – to cause false or fraudulent claims paid or approved by the United States.

144. By virtue of the false records or false statements made by Abbott, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

THIRD CAUSE OF ACTION

(Unjust Enrichment)

145. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

146. This is a claim for the recovery of monies by which Abbott has been unjustly enriched, including (1) profits earned by Abbott through its HI Pharmacies and Consignment Partnership Agreements and (2) profits from increased sales resulting from the illegal inducements that Abbott arranged to be paid to its Customers.

147. By obtaining monies as a result of its violations of federal and state law, Abbott was unjustly enriched, and is liable to account for and pay such amounts, which are to be determined at trial, to the United States.

148. By this claim, the United States requests a full accounting of all revenues (and interest thereon) and costs incurred by Abbott on sales to Customers to whom it arranged for unlawful inducements, and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States on those profits.

FOURTH CAUSE OF ACTION

(Common Law Fraud)

149. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

150. Abbott made material and false representations concerning the prices of the Drugs with knowledge of their falsity or reckless disregard for the truth, with the intention that the United States act upon the misrepresentations to its detriment. The United States acted in justifiable reliance upon Abbott's misrepresentations by making payments on the false claims.

151. Had the true facts of Abbott's false price reporting as set forth in this Complaint been known to the United States, the United States would not have paid for Abbott products.

152. By reason of these payments, the United States has been damaged in an as yet undetermined amount.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Abbott, jointly and severally, as follows:

1. On the First and Second Causes of Action, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Third Cause of Action, for the damages sustained and/or amounts by which Abbott was unjustly enriched, including an accounting of all revenues unlawfully obtained by Abbott, the imposition of a constructive trust upon such revenues, and the disgorgement of the illegal profits obtained by Abbott, plus interest, costs, and expenses, and all such further relief as may be just and proper.

3. On the Fourth Cause of Action, for compensatory and punitive damages in an amount to be determined, together with costs and interest, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

For the United States of America,

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Dated: June 4, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' FIRST AMENDED COMPLAINT** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Mark A. Lavine
Dated: June 4, 2007 Mark A. Lavine

EXHIBIT 116

PERFORMANCE AUDIT

COST CONTAINMENT FOR STATE PRESCRIPTION DRUG EXPENDITURES

From The Office Of State Auditor
Claire McCaskill

Medicaid officials have been slow implementing new cost containment initiatives, updating current measures and recommending legislative or rule changes that are more favorable to the state.

Report No. 2002-48
June 28, 2002
www.auditor.state.mo.us

Office of
Missouri State Auditor
Claire McCaskill

June 2002

YELLOW SHEET

State Medicaid program may pay too much for prescription drugs and reimburse pharmacies more than necessary

Missouri's Medicaid outpatient prescription drug costs have more than doubled in the last 5 years and totaled $770 million in fiscal year 2001. This audit focuses on the Division of Medical Services' efforts to reduce prescription drugs costs. Auditors found Missouri has not been as proactive as other states with certain containment programs, such as preferred drug lists or prior authorization. The following highlights our findings:

Preferred drug lists help other states save money

Many states are now following practices of most employee health insurance plans in using preferred drug lists to reduce costs. Physicians who want to prescribe drugs not on the list have to seek prior approval from the Medicaid program. Michigan and Florida officials estimate these lists will save annually $80 million and $150 million, respectively. Legislation just passed in Missouri's 2002 session allows the division to establish a preferred drug list by January 2003, but division officials predict, in the end, the state rule making process will block its implementation. (See page 5)

State prior authorization rules more complicated then federal

Division officials have not placed many drugs in prior authorization status in the last 5 years, partly due to restrictive state rules which exceed federal requirements. Drugs in this status require a physician seek Medicaid program approval before dispensing them, which often saves costs by resulting in fewer unnecessary prescriptions. State rules require Missouri-specific clinical and therapeutic analysis before placing a drug in prior authorization. Federal law only requires a state plan to respond within 24 hours of a request and dispense a 72-hour emergency prescription. In January 2002, division officials tried to place more drugs in this status, but were blocked from doing so. (See page 6)

Outdated pharmacy reimbursement rates raise costs

Each state Medicaid agency determines how pharmacies are reimbursed for acquiring and dispensing drugs for Medicaid recipients. One way Missouri reaches this price is to use the average wholesale price for a drug less 10.43 percent. But Missouri has not changed this percentage decrease since 1991 and 19 states use a higher percentage decrease than Missouri. For example, a Missouri pharmacy would receive a $119.66 reimbursement from Medicaid for a month's supply for the 20 milligram version of Prilosec®, whereas

pharmacies in a state with a 14 percent decrease would receive $115.05 for dispensing the same supply. Overall, if Missouri changed its percentage decrease from 10.43 percent to 14 percent, division records estimated annual savings of $16.4 million. (See page 7)

Lower reimbursement rate on some drugs could save $1.5 million

Missouri pays more than necessary on 437 drugs dispensed intravenously to at-home or non-hospitalized chronically ill patients. The overpayment occurs because division officials have not timely implemented new dispensing fees for these drugs which would allow providers to be reimbursed using more accurate drug prices. In May 2000, the federal government provided more accurate average wholesale prices for these drugs, with some prices being 80 percent less than previous prices. Our calculations indicate the state could have saved an estimated $1.5 million ($2 million in drugs costs less $500,000 increase in dispensing fees) on the $8.4 million spent on these drugs in fiscal year 2001 if the more accurate prices had been used. Division officials believe any costs savings from the more accurate drug prices would be completely offset by the higher dispensing fees. (See page 9)

State to pay pharmacies the nation's highest dispensing fee to offset new tax

Legislation passed in the 2002 session nearly doubled the dispensing fee paid by the state Medicaid program to pharmacies. The fee increase to $8.04 per prescription from $4.09 would rank as the nation's highest. On average, state Medicaid programs paid a $4.27 fee in 2001. This increase offsets a new 2 percent pharmacy provider tax, also passed in the 2002 session, which would help the state obtain additional federal Medicaid matching funds. Pharmacies would pay about $55.4 million with the new tax, but then receive about $60.4 million from the state in higher dispensing fees. It is uncertain if the federal government will agree to match the tax revenues and the state legislation is not yet signed into law. (See page 10)

New program director appears to have conflict of interest

The Department of Social Services hired a pharmacy program director in October 2001 who previously worked as a lobbyist for the Missouri Pharmacy Association and continues to own at least one pharmacy. Department legal staff determined hiring this person did not violate state conflict of interest laws. However, an appearance of a conflict still exists because of the director's continued financial interests in the pharmacy industry and his new position's influence over policy or legislative changes effecting the industry. (See page 15)

Reports are available on our web site: www.auditor.state.mo.us

COST CONTAINMENT FOR STATE PRESCRIPTION DRUG EXPENDITURES

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CLAIRE C. McCASKILL
Missouri State Auditor

Honorable Bob Holden, Governor
and
Members of the General Assembly
and
Kathy Martin, Director
Department of Social Services
Jefferson City, MO 65102

The state's Medicaid prescription drug costs have more than doubled since 1997 and account for $660 million of the $770 million spent by the state in fiscal year 2001 on prescription drugs. The objectives of this audit were to (1) determine total direct and indirect cost of prescription drugs for the state, (2) evaluate the effectiveness of some of the state's efforts to reduce Medicaid drug costs, and (3) evaluate the factors leading to increased drug costs in the Medicaid program.

Missouri's current budget problems and legislative mandates have led to cost control initiatives during the last year. Medicaid officials are implementing a pharmacy enhancement program consisting of various cost containment initiatives. While this program focuses on some pharmacy reimbursement issues, other reimbursement issues are not being addressed or do not include the therapeutic benefit and cost effectiveness of prescribed drugs. We recommend changes to help improve the effectiveness of this program. In addition, the Pharmacy Program Director has an appearance of a conflict of interest that should be resolved.

224 State Capitol • Jefferson City, MO 65101

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The audit was conducted in accordance with applicable standards contained in *Government Auditing Standards,* issued by the Comptroller General of the United States, and included such tests of the procedures and records as were considered appropriate under the circumstances.

Claire McCaskill
State Auditor

February 19, 2002 (fieldwork completion date)

The following auditors contributed to this report:

Director of Audits:	Kirk Boyer
Audit Manager:	Jon Halwes, CPA, CGFM
In-Charge Auditor:	Christina Davis
Audit Staff:	Shad Becker
	Cindy Elliott
	Andrea Paul
	Lori Melton

RESULTS AND RECOMMENDATIONS

1. Missouri Can Better Contain Medicaid Prescription Drug Costs

Division of Medical Services officials, who run the state's Medicaid program, have not proactively contained drug costs or evaluated pharmacy reimbursements. In the last 5 years, the state's Medicaid outpatient prescription drugs costs have more than doubled. While officials are implementing a pharmacy enhancement program, the program currently does not include establishing a preferred drug list which other states use to lower drug costs. The enhancement initiatives lack emphasis on pharmacy compensation issues. The following concerns were noted:

- Outdated estimated acquisition prices,
- Higher maximum reimbursement rate for insulin drugs,
- More accurate pricing data on home infusion drugs not being used,
- Pharmacies keeping shared dispensing fees, and
- Inadequate monitoring of transactions related to a federal discount program.

In addition, the implemented or planned initiatives to limit prescriptions to a 31-day supply and not pay for over-the-counter products may not be cost effective. As a result, Missouri's Medicaid program may be paying too much for some drugs and reimbursing pharmacies more than necessary.

State prescription drug costs

The state spent approximately $770 million on prescription drugs during fiscal year 2001. Medicaid drug costs[1] made up approximately 85 percent of this total, with the majority for outpatient prescriptions. Table 1.1 shows the prescription drug costs for the state.

[1] Medicaid program expenditures are approximately 60 percent paid for from federal funding. In addition, 60 percent of any Drug Rebates received go to the federal government.

Table 1.1: State Prescription Drug Costs Fiscal Year 2001

Agency or Program Area	Amount Spent
Direct Expenditures:	
Medicaid - Outpatient Services[1]	$ 681,377,799
less Medicaid Drug Rebate[2]	(128,352,149)
Department of Mental Health	7,791,114
Department of Health	2,789,904
Other State Agencies	1,812,943
Total Direct Costs	565,419,611
Indirect[3] Expenditures:	
Employee Health Insurance	91,662,982
Medicaid - Managed Care	62,364,747
Medicaid - Hospital Inpatient[4]	45,000,000
Inmates	5,160,557
Total Indirect Costs	204,188,286
Total Costs	$ 769,607,897

[1] Medicaid program activity is highlighted in yellow.

[2] Federal law requires drug manufacturers to rebate a portion of the drug costs when purchased through state Medicaid programs. The rebate is generally between 15 and 20 percent of the drug's cost.

[3] Costs are built into contract prices.

[4] Estimated based on fiscal year 1999 data.

Source: statewide accounting system, state agency survey and Medicaid records

Medicaid drug costs doubled over 5 years

Between 1997 and 2001, the cost for Medicaid outpatient prescription drugs in the Medicaid program more than doubled, increasing to $553 million from $268 million. This increase has been driven by new drugs, more Medicaid recipients, increased use of maintenance drugs,[2] and higher drug prices. Blind, disabled and elderly Medicaid recipients account for approximately 86 percent of all outpatient prescription drug costs. In fiscal year 2001, the Medicaid program paid $131 million for antipsychotic and antidepressant drugs, before rebates. Twenty-five brand name prescription drugs accounted for nearly 38 percent of all Medicaid outpatient drug expenditures, which are summarized in Appendix III, page 23.

To help control increasing drug costs, the General Assembly mandated various cost containment initiatives. One mandate, in December 2000, targeted the rising costs of antiulcer drugs ($48 million spent in fiscal year 2001) by requiring doctors to receive prior authorization before prescribing these drugs. A second mandate, in fiscal year 2002, required the division to cut pharmacy program expenditures through various division determined initiatives. The division hired a director in October 2001 to manage the Medicaid pharmacy program and oversee the cost

[2] Maintenance drugs are taken daily by patients to treat conditions such as high blood pressure, high cholesterol and anxiety.

cutting initiatives. (See Appendix I, page 19 for a summary of the initiatives and their implementation status as of early 2002.)

Missouri is behind other states in comprehensive cost-containment initiatives

Missouri has not been as proactive as other states in developing preferred drug lists or requiring prior authorization. Both a preferred drug list and prior authorization can help control drug costs while not placing program recipients at risk. These measures would also help program officials better manage use of certain drugs and monitor prescribing practices.

Preferred drug lists could help contain costs

Millions in potential saving available

Recently some Medicaid programs in other states have implemented preferred drug lists, which most employee health insurance plans have used for years. Drugs which are not on these lists may only be prescribed after physicians obtain prior approval from the Medicaid program. Preferred drug lists often take into account the cost and therapeutic value of a drug. Missouri's pharmacy enhancement program does not include plans to implement a preferred drug list. Part of a May 2002 house bill to establish the Department of Social Services budget for fiscal year 2003 would give the Division of Medical Services authorization to establish a preferred drug list prior to January 15, 2003. The Division Director stated that it would be difficult to get such a list approved through the states rule making process and there would be opposition from parties affected by this change.

Since early 2001, Florida and Michigan have joined California[3] in establishing preferred drugs lists. Michigan and Florida officials estimate the lists will save annually $80 million and $150 million, respectively in total state and federal funding. Other states, including Colorado, Louisiana, and Indiana, are also working on similar programs. The Missouri Pharmacy Program Director reported to the legislature an estimated annual savings of $32 million in state funding if a preferred drug list is implemented.

Florida's plan requires drug manufacturers to rebate the state an extra 10 percent of a drug's cost, in addition to the regular federal Medicaid rebate, to place products on the preferred drug list. Drugs from manufacturers unwilling to provide the additional state rebate are only made available to Medicaid recipients on a prior authorization basis. Florida officials allowed two drug manufacturers to guarantee certain costs savings from disease management programs in lieu of paying the rebate.

Michigan, with similar Medicaid prescription drug costs to Missouri, established a state medical panel to analyze cost and therapeutic data and select at least the two best drugs in each of 40 highest cost categories. Other drugs in these categories are placed on prior

[3] California's Medicaid program began using a preferred drug list in 1990. Drug manufacturers provide the state a rebate of 10 to 60 percent of the average manufacturer's price in addition to the federal drug rebate. In fiscal year 2001, California's Medicaid program had $3.2 billion in expenditures for outpatient prescription drugs. The estimated annual saving from using the preferred drug list was $235 million.

authorization status. Drugs already less expensive than the preferred medicines are also placed on the preferred drug list. Manufacturers can also have other products moved to the preferred drug list if they cut prices to match the best-in-class drugs. The program is used for Medicaid and other state funded healthcare programs.

Missouri's prior authorization rules are too complicated

Division officials have not placed many drugs or classes of drugs in prior authorization[4] status in the last five years. The pharmacy enhancement program proposes expanding the number of drugs on the state's prior authorization list, but restrictive state rules hinder this process. A prior authorization process is an integral part of any preferred drug list because drugs not on the list may not be prescribed without prior authorization.

Missouri's rules[5] for placing drugs on prior authorization are more complicated and restrictive than federal government requirements. A division official stated part of the reason the rules are more complicated than necessary is because pharmaceutical industry representatives assisted state officials in drafting the rules 10 years ago. State rules require Missouri-specific data based on medical and clinical criteria, a public hearing, and an annual review of approved drugs. Federal law does not require these procedures. Federal law only requires a state's prior authorization plan respond within 24 hours of a request and allow for dispensing of a 72-hour emergency prescription. As a result, clinical and therapeutic analysis is not required to place drugs on prior authorization under federal law. Missouri has used prior authorization as more of a clinical tool to prevent adverse drug interaction for recipients, while other states such as South Carolina, also used it to contain drug costs.

In January 2002, the division attempted to add some antihistamine and antifungal drugs to the state's prior authorization list. The General Assembly's Joint Committee on Administrative Rules denied this request citing noncompliance with some of the prior authorization requirements. Division officials believe all requirements were met, but withdrew the request with an intent to submit it again. As a result, the state lost potential savings by not placing these drugs into prior authorization status.

Our survey of 20 states indicated that certain drugs or drug classes are frequently placed in a prior authorization program. Product cost was at least one component in the decision to implement prior authorization for the drugs or drug classes in those states. Table 1.2 lists these drugs or drug classes and the amount the Missouri Medicaid program spent on these drugs or drugs classes in fiscal year 2001. As of February 2002, only the antiulcer drug class required prior authorization in Missouri.

Vioxx®, Celebrex®, Claritin®, and OxyContin® are among Missouri's top 25 Medicaid drug costs as noted in Appendix III, page 23. While prior authorization of a drug or drug class

[4] A prior authorized drug will be approved for dispensing if the division's detailed algorithm based on clinical data specific to the drug indicates a patient's therapeutic need for it.

[5] Generally established through state agency developed proposals contingent upon the General Assembly's review of the proposed order of rulemaking through the Joint Committee on Administrative Rules.

may result in some increased costs to manage prior authorization requests, these additional costs are more than offset by fewer unnecessary prescriptions for these drugs.

Table 1.2: Drug or Drug Classes Other States Require Prior Authorization and Missouri's Cost for These Drugs

Drug or Drug Class	Number of States	Missouri's Fiscal Year 2001 Cost
Antiulcer (Prilosec®, Prevacid®, etc.)	8	$ 48,052,775
Cox II Inhibitors (Vioxx® and Celebrex®)	8	22,347,736
Antihistamines (Claritin®, Allegra®, Zyrtec®)	6	13,029,558
OxyContin®	2	9,344,838

Source: State survey results and Medicaid data

Cost containment initiatives lack emphasis on adjusting pharmacy compensation

Most of the pharmacy enhancement program initiatives do not consider pharmacy reimbursement rates or evaluate appropriateness of pharmacy billings to the program. One initiative is to expand the number of drugs on the state upper payment list as generic drugs become available for brand-name drugs.[6] Updating state upper payment limit rates more frequently will help contain the state's drug costs. These updates will have increasing importance as popular brand-name drugs lose patent protection over the next 5 years and more generic alternatives become available. Currently, drugs added to the list and the upper limit reimbursement prices are updated on an irregular basis with a planned goal of updating them at least quarterly. The most recent updates were done in September 2001; and January and May 2002. Some states surveyed revise drugs and rates on upper payment limit lists more than quarterly. For example, Nebraska officials do updates every other month and Illinois officials make changes weekly.

However, approximately 80 percent of the expenditures for outpatient prescription drugs received by Medicaid recipients in fiscal year 2001 were for brand-name and generic drugs not eligible for the state upper payment limit list. Medicaid program officials have not evaluated the pharmacy compensation for these drugs, making it possible the state is paying too much for them.

Pharmacy reimbursement rates are outdated

Each state Medicaid agency determines how much pharmacies are reimbursed for the estimated cost involved in acquiring (estimated acquisition price) and dispensing drugs.[7] This price is based on manufacturers' costs and is generally calculated using two different rates; one rate uses the average wholesale price for a drug less a percentage and the other rate is based on the wholesale acquisition cost plus a percentage. While most states use one or

[6] This is a list of brand-name drugs with expired patents and associated generic drugs for which the division has established a lower reimbursement limit generally close to the lowest cost generic drug.

[7] See Appendix II, page 20, for a more detailed description of pharmacy reimbursement options.

the other rate, Missouri has used both since July 2001. Further, the same rates are used for both brand-name and generic drugs. According to division estimates, each percentage change in these price adjustments impacts expenditures by an estimated $5 million annually.

In addition to using the same price for brand and generic drugs, the average wholesale price percentage decrease used by Missouri may be outdated based on federal reports and discounts used by other states. Missouri's average wholesale price decrease of 10.43 percent is based on a 10-year old (1991) state-sponsored study of pharmacy wholesale prices. Further, the wholesale acquisition cost increase of 10 percent is based on percentages used in other states and not a state study.

A 1997 federal report[8] based on Missouri pharmacy wholesale prices concluded pharmacy discounts from average wholesale prices were 18.5 percent for brand name drugs and 46.4 percent for generic drugs. National figures for other states reviewed at that time indicated similar percentage reductions. A 2001 federal report[9] indicated national pharmacy discounts had increased substantially to 21 percent for brand-name drugs and to 65 percent for generic drugs. While state officials must include other factors beside wholesaler price discounts when setting estimated acquisition prices, 19 states use a higher average wholesale price percentage decrease than Missouri's 10.43 percent. One state uses a 15 percent decrease. If Missouri's percentage decrease was changed from 10.43 percent to 14 percent, division records showed annual savings of $16.4 million.

Reimbursement rates for insulin drugs are also outdated

The state reimbursed pharmacies $320,000 more than necessary in state fiscal year 2001 as the result of using a higher maximum reimbursement rate for insulin drugs.[10] The estimated acquisition price used for pharmacy reimbursements for these products is average wholesale price minus 10.43 percent plus 25 percent which is higher than the estimated price used for most drugs (average wholesale price minus 10.43 percent plus a $4.09 dispensing fee per prescription). Division officials seemed to be unaware of this higher reimbursement rate when we questioned them on the issue. Officials from three states surveyed indicated they used the same reimbursement rate for insulin drugs as other prescription drug products. If the same estimated acquisition price had been used for insulin drugs as other prescription drugs in the Medicaid program, the state would have saved $320,000 on the $7.1 million spent on these drugs in fiscal year 2001.

[8] Department of Health and Human Services Office of Inspector General - *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Social Services* issued January 1997.

[9] Department of Health and Human Services Office of Inspector General - *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Washington Department of Social and Health Services* issued November 2001.

[10] Insulin products are considered over-the-counter products for which pharmacies do not receive a dispensing fee.

Lower reimbursement rates for certain home infusion drugs not used

Missouri continues to pay more than it should on home infusion drugs[11] because division officials have not implemented more accurate drug prices. In May 2000, the federal Department of Justice provided all states with more accurate average wholesale prices for 437 primarily home infusion dispensed drugs. Some prices were more than 80 percent less than the average wholesale prices previously reported by pharmaceutical companies. The state could have saved an estimated $1.5 million on the $8.4 million spent on these 437 drugs in fiscal year 2001 if officials used the more accurate average wholesale prices and a dispensing fee structure similar to one implemented in another state.

Within 2 months of Department of Justice notice of the more accurate average wholesale prices, Utah officials began using the lower drug prices with new dispensing fees. With the help of infusion specialty providers, Utah officials categorized the 437 drugs into 5 groups appropriate to the preparation and overhead costs for the product. The new dispensing fees set up for drugs in 4 of the 5 categories ranged from $8.90 to $33.90 per prescription.

The state could save $1.5 million annually

Missouri officials initially implemented the more accurate prices for provider reimbursement using the normal $4.09 dispensing fee, which was not designed to cover these drugs. Division officials reversed this decision after home infusion providers threatened to cease services due to insufficient dispensing fees. Provider personnel admitted the former reimbursement rates exceeded their product acquisition costs, but they used the excess reimbursement to offset the higher dispensing costs of home infusion drugs. Division officials indicated they plan to use these lower prices again after determining adequate compensation for home infusion services. While no implementation date has been set, the Division Director stated the necessary changes to implement these prices would be part of the division's fiscal year 2004 budget proposal.

State is not collecting some pharmacy fees while proposing to increase other fees

For years, division officials have allowed pharmacies to keep some recipient co-payments, known as shared dispensing fees, in lieu of increasing the $4.09 prescription dispensing fee. Pharmacies kept an estimated $3 million to $6 million in shared dispensing fees in fiscal year 2001. Certain Medicaid recipients pay an optional shared dispensing fee for pharmacy transactions ranging from 50 cents to $2 based on the cost of the prescription.[12] However, this compensation is not being considered as part of legislation to establish a pharmacy provider tax and nearly double the dispensing fee to $8.04 per prescription.

Division officials do not maintain any data on the shared dispensing fee amounts kept by pharmacies. They estimate this fee applies to half of all pharmacy transactions, and

[11] Drugs generally dispensed intravenously by health care professionals to patients with chronic illnesses who can live at home or in a non-hospital arrangement.

[12] Children, pregnant women and institutionalized recipients are exempt from paying the shared dispensing fee. However, no Medicaid recipient can be denied a prescription if he/she cannot pay the shared fee amount.

recipients pay the fee about half of the time. During fiscal year 2001, the Medicaid program had more than 13 million pharmacy transactions. We estimate that pharmacies received between $3 million and $6 million based on (1) an average prescription price greater than $10, (2) a shared dispensing fee between $1 and $2 per prescription, and (3) the fee applied to 25 percent of the more than 13 million pharmacy transactions in fiscal year 2001.

$8.04 fee would be nation's highest

The fiscal year 2003 state budget includes a pharmacy provider tax to obtain additional federal Medicaid matching funds although it is uncertain the federal government will match these tax revenues.[13] The budget estimates pharmacies will pay about $55.4 million under a 2 percent tax on their prescription drug business. However, the budget also shows the state will pay pharmacies $60.4 million in additional dispensing fee compensation. The dispensing fee would nearly double from $4.09 to $8.04. If the pharmacy tax is implemented, the state's $8.04 dispensing fee will far exceed fees paid by any other state. During fiscal year 2001, the average dispensing fee for all state Medicaid programs was $4.27, with the highest being $5.77 in Louisiana. The $8.04 fee does not include the shared dispensing fees currently retained by pharmacies. Some states that require recipient co-payments or shared dispensing fees will reduce a pharmacy's transaction reimbursement for the amount the pharmacy receives from a recipient. However, this situation was not considered by the state under this pharmacy tax/increased dispensing fee legislation.

Controls over transactions for a pharmacy discount program need improvement

The state may have lost more than $500,000 in fiscal year 2001 by overpaying some pharmacies or incorrectly billing manufacturers for rebates related to a federal discount drug program. Section 340B of the Public Health Service Act requires drug manufacturers discount the cost of drugs supplied to certain federally covered entities, and that the entities pass on the discounts by billing Medicaid at the discounted prices. We focused on approximately 20 pharmacies that received more than 95 percent of the outpatient pharmacy expenditures paid to program participating providers. The errors occurred because division staff did not determine if program providers billed the state appropriately and did not effectively evaluate the continued participation status of program providers. As a result, the state (1) did not claim some rebates from pharmaceutical manufacturers, (2) claimed some rebates for ineligible transactions, and (3) failed to receive the required discount from at least three program participating providers. Table 1.3 summarizes these results.

According to federal officials, discounted prices through this program generally average about 40 percent less than the manufacturers' average wholesale price. For entities participating in the Section 340B program, the state is not allowed to bill the manufacturer for drug rebates for transactions billed at the discounted rate. The state has established a computer edit to remove transactions for participating providers from the rebate billing process.

[13] The federal matching funds are estimated at $86.5 million. The federal government will have to approve a waiver to the state's Medicaid Plan for this tax revenue to qualify for additional matching funds.

Table 1.3: Fiscal Year 2001 340B Program Provider Errors

Error Type	Number of Providers	Pharmacy Expenditures to Provider	Estimated Value of Errors
Provider failed to bill at discounted rate	3	$ 1,275,651	$ 389,549
Rebate not claimed	7[1]	1,279,297	177,502[2]
Rebates inappropriately claimed[3]	1	1,157,761	(40,169)[2]
Total		$ 3,712,709	$ 526,882

[1] Four of the 7 providers receive only family planning drugs through the 340B program, but all facility transactions are excluded from the rebate process. These providers billed little or no family planning drugs to the Medicaid program.

[2] These errors may be corrected through billing corrections for any rebates not claimed and the manufacturer billing dispute process.

[3] Provider began participating in the 340B program April 1, 2001.

Source: Medicaid data and discussions with providers

Two initiatives may be counter-productive and increase costs

In fiscal year 2001, Medicaid program rule changes limited most prescription drugs to a maximum 31-day supply. Department budget documents also proposed, beginning in fiscal year 2003, not paying for over-the-counter products, except insulin. These changes could cost the program more, particularly with the proposed increase in dispensing fees to $8 or more per prescription.

The 31-day supply limit prevents many recipients from receiving 90-day prescriptions for maintenance drugs which triples the program's dispensing costs for these recipients. According to division officials, the theory behind such a policy change is the increased dispensing costs will be offset by less money spent on unused portions of 90-day prescriptions. Unused drugs may occur if recipients are given 90-day prescriptions for drugs prior to their doctor determining the drug was effective to treat them. The Pharmacy Program Director stated it was inconclusive whether the Medicaid program saved money with the 31-day supply limit during fiscal year 2001. At least three of the states surveyed have monthly supply limits, but make an exception for maintenance drugs. In December 2000, Missouri made this same exception on maintenance drugs for 25,000 Medicaid spenddown[14] recipients.

Missouri and 12 states responding to our survey questions on over-the-counter products currently use payment for these products as a cost containment measure. A Medicaid program would rather have a physician prescribe a less expensive over-the-counter product than a more expensive prescription product if that product could effectively treat the patient. During fiscal year 2001, the Medicaid program paid $6.4 million for non-insulin over-the-counter drugs. Most of these products were for the treatment of lice, indigestion, pain, or iron deficiency. State officials estimate the Medicaid program will save more than $6 million by not paying for over-the-counter products. However, if doctors begin prescribing

[14] Spenddown is a status given to a recipient whose income is too high to qualify for normal Medicaid benefits but can qualify after incurring a determined amount of medical costs during a three-month period.

prescription drugs for Medicaid recipients when an over-the-counter product would suffice, this potential saving is lost by paying higher prices for prescription drugs. This scenario could occur since Medicaid recipients pay little or no cost for prescription drugs and may tell doctors they cannot afford the prescribed over-the-counter product. In addition, recent news that the popular prescription product Claritin® will be converted to over-the-counter status in late 2002 may require this decision to be modified.

Conclusion

Cost containment for Medicaid prescription drug costs must be evaluated on an ongoing basis as changes take place in the pharmaceutical industry and in other state Medicaid programs. The Division of Medical Services has not done all it can to contain Medicaid drug costs. While division officials have faced challenges in restrictive state laws, they have been slow in implementing new cost containment initiatives, updating current initiatives and recommending legislative or rule changes that enhance program effectiveness. Some state Medicaid programs are implementing preferred drug lists which consider therapeutic value and/or cost of drugs being prescribed. Several cost containment measures are currently being implemented with unknown savings. Various pharmacy compensation issues need to be evaluated as part of the pharmacy enhancement program to better contain drug costs.

Recommendations

We recommend the Director, Department of Social Services:

1.1 Develop plans to implement a preferred drug list that considers the therapeutic value and cost of drugs.

1.2 Amend the state's Medicaid prior authorization rules to limit unnecessary issues that delay moving drugs or drug classes to a prior authorization basis.

1.3 Update drugs and reimbursement rates on the state upper payment limit list more frequently.

1.4 Update the current estimated acquisition prices and pharmacy dispensing fees. Separate estimated acquisition price computations for generic and brand name drugs should be established as well as eliminating the current higher maximum reimbursement rate for insulin products.

1.5 Implement the lower average wholesale prices for home infusion products with equitable dispensing fees for home infusion services.

1.6 Improve procedures to ensure (1) 340B program providers pass on appropriate discounts to the state and (2) drug rebates are received for all appropriate pharmacy transactions including eligible transactions for providers only receiving some discounted drugs through the program.

1.7 Adjust pharmacy reimbursements for shared dispensing fees retained by pharmacies if the planned pharmacy tax/increased dispensing fee is implemented.

1.8 Closely monitor the cost effectiveness of (1) eliminating 90-day prescription authorization for maintenance drugs and (2) not paying for over-the counter drugs.

Department of Social Services Responses

1.1 Consistent with the mandates of the General Assembly, the Division of Medical Services plans to begin work on a preferred drug list in FY 03.

1.2 The Division concurs with the SAO recommendation. Consistent with the opportunities and constraints of the rulemaking process, the Division is amending the prior authorization rules to make the process more streamlined.

1.3 The Division is presently updating the upper payment information globally on a quarterly basis and as needed on an individual product basis. This is more frequently than other third party payers. The Division feels it would be impractical to update these limits more frequently.

1.4 The Division pointed out to the SAO the pharmacy reimbursement regarding the acquisition prices and the dispensing fees are set through the appropriation process by the General Assembly. The Division continues to collect information regarding these reimbursement issues for use by the General Assembly in their deliberations.

With regard to the insulin products, they are presently subject to the "lower of" test with the AWP plus 25% reimbursement being the maximum allowable reimbursement. The Division has found few pharmacies billing at this ceiling rate. However, the Division will change the insulin reimbursement to the standard pharmacy reimbursement methodology approved by the General Assembly.

1.5 The Division agrees a change in the reimbursement methodology should occur with respect to the home infusion services. The Division continues to work on this process and will develop a decision item for consideration in the SFY04 budget. When implemented, the resulting changes are expected to be revenue neutral for the state and the providers.

1.6 The Division has accepted the recommendation of the SAO and is developing guidelines for 340B program providers.

The Division policy is to place providers that purchase products through 340B in a system edit (Parm) so claims will not enter the Medicaid rebate system. When a provider is added to the Parm, all their products are exempt from reporting to Drug Rebate. The Division will research a system modification to resolve the issue of providers purchasing specific products only through 340B.

Any uncollected rebates noted in the review are recoverable and overpayments of rebates will be resolved with the manufacturers during the dispute resolution process.

1.7 The shared dispensing fee collection is not required of the recipient to receive services. Federal law will not allow the assessment of the fee as a prerequisite for receiving services. Pharmacy providers in various areas of the state collect the fee at a different rate. The Division will consider the impact and the collection rate when providing information to the General Assembly for future changes in the pharmacy dispensing fee.

1.8 The 30-day prescription limit and limited payment for over-the-counter drugs were mandated by the General Assembly during the appropriation process. The Division will monitor both for fiscal impact to the state.

2. Pharmacy Program Director Appears to Have a Conflict of Interest

Prior to being hired by the Department of Social Services in October 2001, the Pharmacy Program Director served as a registered lobbyist for the Missouri Pharmacy Association and continues to own at least one pharmacy. Division of Medical Services officials did not consult the Missouri Ethics Commission concerning potential conflicts, although they were aware of his business relationships. The Division Director stated the department's legal staff evaluated the hiring and determined there would be no conflict of interest problem if the hiring took place. Nevertheless, the pharmacy program is managed by someone with a financial interest in the same industry on which he can influence policy decisions made by his department and the legislature. Department officials have no assurance that such influence is unbiased or in the state's best interest.

The Pharmacy Program Director said his business interests do not create a conflict of interest because he lacks rule-making authority and does not qualify as a "decision-making public servant" under state law. However, this Director is in a position to influence program decisions and legislative changes that may impact the profitability of pharmacies, such as proposing changes to pharmacy reimbursement rates. He needs to be free of unintentional or intentional bias towards the industry. The Division Director stated the Pharmacy Program Director is providing the state needed expertise to get the pharmacy program in the right direction.

Conclusion

Department officials should ensure conflicts of interest do not occur. Issues regarding potential conflicts of interest should be resolved before employees are hired.

Recommendation

The Director, Department of Social Services:

2.1 Resolve the appearance of a conflict of interest for the Pharmacy Program Director.

Department of Social Services Responses

2.1 The Division consulted with the Department's Division of Legal Services regarding the issue of conflict of interest of the Pharmacy Program Director. The Pharmacy Program Director has filed a full disclosure with the Ethics Commission and has made his holdings clear to all interested parties. Additionally, the Pharmacy Program Director obtained a legal opinion from his legal counsel and has shared that opinion with the Department and Division. The opinion indicates no conflict of interest exists.

The results of the pharmacy program operations, the decline in industry reimbursement, and the program management statistics all support the fact the Pharmacy Program Director is fulfilling his job requirements without bias or regard to pharmacy or pharmaceutical industry outcomes. The Pharmacy Program Director has been forthcoming in all recommendations and has delivered on all Division requests with

balanced recommendations, which allowed appropriate decisions to be made by the Division and Department administration.

APPENDIX I

OBJECTIVES, SCOPE AND METHODOLOGY

Objectives

The objectives of this audit were to (1) determine total direct and indirect cost of prescription drugs for the state, (2) evaluate the effectiveness of some of the state's efforts to reduce Medicaid drug costs, and (3) evaluate the factors leading to increased drug costs in the Medicaid program.

Scope and Methodology

To accomplish the objectives, we:

- Reviewed applicable state and federal laws related to outpatient prescription drug benefits in the state's Medicaid program.

- Reviewed the state's Medicaid pharmacy enhancement program current and planned initiatives. These initiatives and the implementation or planned implementation dates are summarized in Table I.1. Due to delays in implementation of some initiatives, and the timing of our audit, our review focused on the items discussed in the report.

- Interviewed the Pharmacy Program Director and other responsible officials to determine the status of the pharmacy enhancement program initiatives and pharmacy reimbursement processes, and obtained necessary documentation.

- Interviewed officials responsible for various state employee health plans (Missouri Consolidated Health Plan, Department of Conservation, Department of Transportation and the University of Missouri) to determine the total cost of prescription drugs to the state, and to compare the pharmacy benefits of the employee plans.

- Contacted Medicaid program officials of 20 states to determine how Missouri compares to other states in implementing cost containment initiatives.

- Analyzed Missouri Medicaid pharmacy claims for fiscal years 2000 and 2001 to determine the most prescribed and most expensive drugs to the program, and the reasons for the increase in prescription drug costs.

- Reviewed average wholesale prices, wholesale acquisition costs, and federal and state upper payment limits for selected drugs to understand the pharmacy reimbursement process and how Missouri's reimbursements compare to other states.

- Analyzed pharmacy claims for selected Medicaid providers participating in a federal prescription drug discount program. We identified approximately 20 pharmacies that handled the majority of the program's transactions. For each pharmacy we selected 5 brand-

name drugs and compared the reimbursed rate to a computation of the average wholesale price less 10.43 percent plus the $4.09 pharmacy fee. If the reimbursed rate was 25 to 40 percent less than the estimated normal reimbursement we concluded the pharmacy billed the state at an appropriate discounted rate. For any other results, we contacted representatives of the pharmacy to determine program participation status. To evaluate if rebates were correctly billed, we obtained a listing of all providers in Missouri participating in the program. This listing was compared to a listing of providers in the program maintained by the division whose transactions are not included in drug rebate billings. The estimates for potential overpayments or rebate over or under billings were adjusted for dispensing fee compensation received by pharmacies.

- To determine the amount potentially overpaid for 51 insulin drugs, we obtained all transactions for these products for fiscal year 2001. We compared the amount paid for each transaction to a computation of the average wholesale price less 10.43 percent plus the $4.09 pharmacy fee.

- To determine the potential saving for the 437 home infusion products, we obtained the spring 2000 wholesale prices submitted to states by the Department of Justice. For these 437 drugs in fiscal year 2001, we compared the pharmacy reimbursement for each transaction using the wholesale prices submitted by the Department of Justice to the prices currently being used by the state. To determine the potential increase in dispensing fee costs, we obtained the dispensing fee structure for these drugs used by Utah, and multiplied that rate less $4.09 times the number of transactions for each drug. The estimated drug cost savings was $2 million with additional dispensing costs estimated at no more than $500,000.

We conducted our fieldwork between August 2001 and February 2002.

APPENDIX I

Table I.1: Medicaid Prescription Drug Cost Containment Initiatives

Initiative	Implementation or Planned Implementation Date
31-day maximum supply	December 2000
Expansion of state upper payment limit list	December 2000; September 2001; and January and May 2002[1]
Eliminate pay and chase	March 2001 - Halted due to litigation
Nursing home credits for returned drugs	July 2001[2]
Unique prescriber number	January 2002
Prior authorization expansion	January 2002 - Withdrawn due to rule compliance issues
Dose optimization	April 2002
Edits-max quantity/hard edits	June 2002[3]
Physician education components	June 2002[3]
Disease management	June 2002[3]
Patient profiling	June 2002[3]
Enhanced retrospective drug utilization	June 2002[3]
Additional justification on overrides	March 2002
Provider audits	Fiscal Year 2003
Prior authorization of all new drugs	Fiscal Year 2003
Eliminate over-the- counter, except insulin	Fiscal Year 2003
Pharmacy provider tax	Fiscal Year 2003
Pill splitting	unknown - Reassessing based on fewer products being eligible for splitting than originally planned

[1] Division officials estimate this initiative saved the program $4.28 million through December 31, 2001.
[2] Division officials estimate this initiative saved the program $100,000 through December 31, 2001.
[3] The initiative is pending installation of Medicaid computer system enhancements which are expected in the fourth quarter of fiscal year 2002.

Source: Department of Social Services budget documents, discussions with Division of Medical Services officials

APPENDIX II

BACKGROUND

The Department of Social Services - Division of Medical Services is responsible for administering the state's Medicaid program. The program is authorized under Title XIX of the federal Social Security Act,[15] and is jointly funded by state and federal funds. Services provided by the program include those required by federal regulations such as hospital, physician, and skilled nursing home care. The state's Medicaid program also provides optional services such as dental, prescription drugs, and personal care as authorized by the General Assembly.

The state's Medicaid program provides eligible Missouri residents prescription drug services at nominal or no cost. The cost for Medicaid outpatient prescription drugs increased $285 million between fiscal year 1997 and 2001 as shown in Table II.1. These costs are estimated to be $744 million during fiscal year 2002.

Table II.1: Medicaid Outpatient Prescription Drug Costs
Fiscal Years 1997 to 2001 (in millions)

		Fiscal Year				
		1997	**1998**	**1999**	**2000**	**2001**
Expenditures	$	321	374	469	581	681
Less rebates		(53)	(64)	(84)	(110)	(128)
Net expenditures	$	268	310	385	471	553
Change from prior year			16%	24%	22%	17%

Source: Medicaid records

Pharmacy reimbursement options

Medicaid regulations provide for the pharmacy reimbursement of outpatient drugs using two methods (multiple source and single source).

If a drug is a multiple source drug (brand-name drug and 3 or more generic versions of the drug), then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or a federal upper limit amount plus a dispensing fee. The federal upper limit amounts are established by the Department of Health and Human Services - Centers for Medicare and Medicaid Services. The reimbursed amount for the brand-name and associated generic drugs will be the federal upper payment limit amount no matter what the billed cost of the drug. The rate is set based on the prices for each product and normally set near the lowest price for any of the products. Missouri also has established another option (state upper payment limit) which is similar to the federal upper payment limit, but may be set once a brand-name drug

[15] Laws governing the Medicaid prescription drug programs are 42 United States Code (USC) Section 1396r-8 (Payment for covered outpatient drugs) and 13 Code of State Regulation (CSR) 70-20 (Pharmacy Program).

has at least 1 but generally 2 or more generic versions verses the federal criteria of 3 or more versions. Pharmacy reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public, the state upper payment limit plus a dispensing fee or the federal upper limit amount plus a dispensing fee (if applicable).

If a drug is a single source drug (brand-name drug), or a generic drug for which a state or federal upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition cost plus a dispensing fee. Effective July 1, 2001, Missouri uses two potential estimated acquisition prices:

- Average wholesale price (AWP) minus 10.43 percent
- Wholesale acquisition cost (WAC) plus 10 percent

Tables II.2 and II.3 illustrate the reimbursement options and decision process for a one month prescription for two drugs.

Table II.2: Pharmacy Reimbursement Options

		Estimated Acquisition Price		Upper Payment Limit	
Drug Type	**Drug Name**	**AWP-10.43%**	**WAC+10%**	**State**	**Federal**
Brand	Prilosec	$ 115.57	118.27	N/A	N/A
Generic	Amoxapine	$ 70.05	68.82	23.40	31.72

Table II.3: Pharmacy Reimbursement Decision

Drug Name	**Lowest Option + Dispensing Fee[1]**	**Billed Amount**	**Reimbursement[2]**
Prilosec	$ 119.66	115.00	115.00
Amoxapine	$ 27.49	35.85	27.49

[1] The lowest cost of the 4 options is chosen and the $4.09 dispensing fee is added to determine the maximum reimbursement amount.

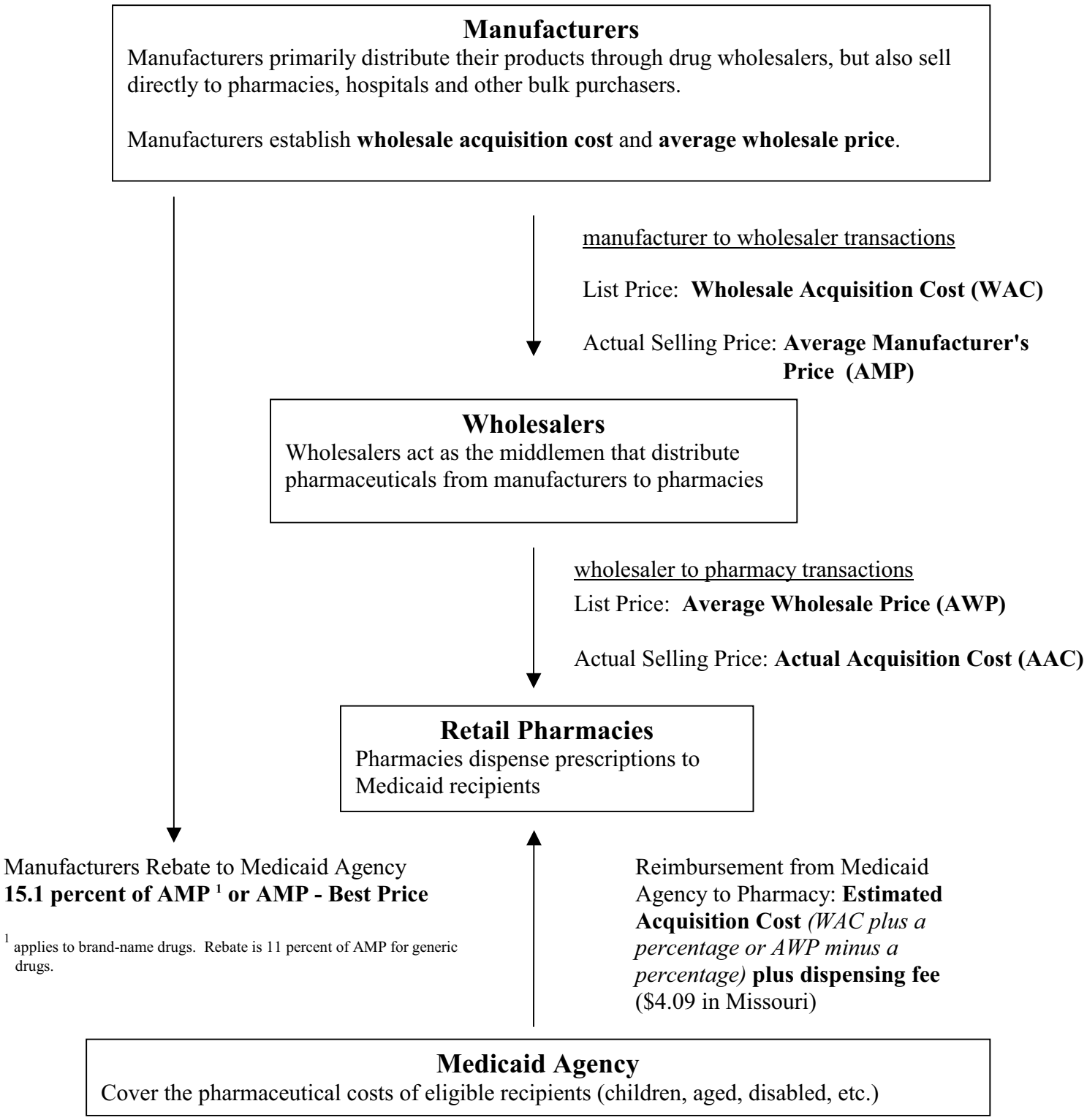
[2] The lower of the amount billed or the maximum reimbursement amount.

Source: Medicaid drug price data

Figure II.1 describes the reimbursement process to pharmacies for drugs received by Medicaid recipients and the rebate provided by manufacturers to state Medicaid agencies.

APPENDIX II

Figure II.1: Description of the Medicaid Reimbursement Process



Source: Department of Health and Human Services - Office of Inspector General; SAO compiled data

APPENDIX III

TOP 25 MEDICAID OUTPATIENT PRESCRIPTION DRUGS - FISCAL YEAR 2001

Table III.1 lists the 25 outpatient prescription drugs the Missouri Medicaid program spent the most for in fiscal year 2001. These drugs represent nearly 38 percent of the $681,377,799 spent on outpatient prescription drugs that year.

Table III.1: Top 25 Medicaid Prescription Drugs - Fiscal Year 2001

Brand Name		Amount Spent	Use
Zyprexa®	$	35,910,411	Antipsychotic
Risperdal®		22,991,612	Antipsychotic
Prilosec®		18,806,905	Stomach Acid Blocker
Prevacid®		14,432,770	Stomach Acid Blocker
Celebrex®		13,197,253	Arthritis Treatment
Prozac®		11,847,723	Antidepressant
Zoloft®		10,886,247	Antidepressant
Depakote®		10,767,140	Anticonvulsant
Paxil®		10,420,245	Antidepressant
Lipitor®		10,022,348	Cholesterol Lowering Agent
Neurontin®		9,895,260	Anticonvulsant
Oxycontin®		9,344,838	Narcotic Pain Reliever
Vioxx®		9,150,483	Arthritis Treatment
Seroquel®		9,100,210	Antipsychotic
Norvasc®		6,852,602	Blood Pressure Reducer
Buspar®		6,436,251	Antianxiety
Claritin®		6,160,792	Antihistamine
Glucophage®		6,136,640	Lowers Blood Sugar
Zocor®		5,294,398	Cholesterol Lowering Agent
Celexa®		5,200,362	Antidepressant
Ultram®		5,092,688	Analgesic Pain Reliever
Remeron®		5,077,321	Antidepressant
Pepcid®		5,007,771	Stomach Acid Reducer
Zithromax®		4,926,713	Antibiotic
Effexor®		4,899,261	Antidepressant
Total	$	257,858,244	

Source: Medicaid program expenditure data